Regulations for Licensing and Certifying of Substance Abuse Treatment Programs

Effective Date
December 29, 2006

Department of Health and Human Services
Division of Licensing and Regulatory Services
Community Services Programs

Regulations for Licensing and Certifying
of
Substance Abuse Treatment Programs
Table of Contents

Section 1

Section 2

Licensing Procedure and Review

Section 3

Agency Organization

Section 4

Fiscal Management

Section 5

Quality Management

Regulations for Licensing and Certifying
of
Substance Abuse Treatment Programs
Table of Contents

Section 6

Insurance

Section 7

Section 8

Personnel Management

Section 9

Organizational Structure

Section 10

Section 11

Clinical Supervisor

Regulations for Licensing and Certifying
of
Substance Abuse Treatment Programs
Table of Contents

Section 12

Reference and Background Checks

Section 13

Direct Care Contracted Staff (Affiliate Councilors)

Section 14

Administrative Management

Section 15

Operational Practices

Section 16

PNMI

Section 17

Environment and Safety

Section 18

Client Rights and Access to Treatment

Section 19

Substance Abuse Treatment Services

Regulations for Licensing and Certifying
of
Substance Abuse Treatment Programs
Table of Contents

1.0 COMPREHENSIVE DEFINITIONS

1.1 Administrator: The individual appointed by the Governing Authority to act in its behalf in the overall management of the substance abuse program.

1.2 Advisory Board: A group that makes recommendations regarding any aspect of the agency's operations or practices, as charged by the Governing Body, but having no proprietary interest in the program or service or actual managerial or administrative authority.

1.3 Affiliate counselor: A contracted provider who provides clinical services for a licensed/certified agency.

1.4 Agency: An incorporated firm, partnership, association, or organization licensed/certified under these regulations that provides at least one substance abuse treatment service. Agency is also known as licensee/provider.

1.5 Appeal: A written request by an agency for a hearing to review any negative licensing action taken by the Licensing Authority or Department as provided by the Maine Administrative Procedures Act, Title 5 M.R.S.A. § 9051 et seq.

1.6 Applicant: Any individual(s), partnership, corporation, association, or organization that has submitted a written application to operate a licensed/certified substance abuse program or service.

1.7 Assessment (Clinical): A written record of intake data performed by a clinician to arrive at a diagnosis, determine the degree of impairment, and determine treatment needs and services.

1.8 Case Record: A unified, comprehensive collection of documentation concerning a client in a substance abuse program.

1.9 Certificate of Approval: A certificate issued by DHHS to a nonresidential program that indicates satisfactory compliance with applicable regulations.

1.10 Client: Any individual who has applied for, or has received services such as an assessment, diagnosis or treatment in a substance abuse program.

1.11 Clinician: A person who is qualified through education, training, experience, and licensure to provide treatment services.

1.12 Compliance: To be in accordance with the requirement of a regulation.

1.13 Component: A category of comprehensive services within an agency, such as substance abuse services or mental health services that includes one or more treatment modules.

1.14 Conditional License/Certificate: A license/certificate issued when an applicant fails to meet substantially the requirements of these regulations, or when the program cannot be maintained in legal compliance (policy), or when multiple citations are repeated from a previous review and have not been corrected. This license/certificate shall be issued for a specific period, not to exceed one year, or the remaining period of the previous full license/certificate. The license/certificate shall specify what and when corrections must be made in order to continue to operate.

1.15 Counseling: The interaction between a clinician and a client for the purpose of facilitating and sustaining behavior change. Counseling results in the establishment and clarification of goals for future behavior, and is based upon an objective, individualized treatment plan derived from an assessment of the treatment needs of the client.

1.16 Critical Incidents: Critical incidents shall include, but not necessarily be limited to, adverse or potentially adverse occurrences that imperil life, limb, or well-being; that seriously breach agency policy; or that breach client rights.

1.17 Deemed Status: The Division of Licensing and Regulatory Services determines whether an accreditation body's standards are the same or similar to these licensing regulations, and whether to deem a provider to be in compliance with some or all of these licensing regulations based upon a review of the findings of an accreditation body approved by the Licensing Authority.

1.18 Detoxification: A service that provides persons having acute physical problems related to alcohol or other drug withdrawal with immediate diagnosis and treatment, as well as appropriate referral and transportation to emergency health care facilities when required.

1.19 DHHS: Maine Department of Health and Human Services.

1.20 Documentation: A written record acceptable as evidence to ensure compliance with these regulations.

1.21 Driver Education and Evaluation Programs (DEEP): The State of Maine OUI countermeasures program required for persons who have been convicted of operating under the influence of alcohol and other drugs and those whose licenses are administratively suspended because of drinking and driving.

1.22 Elopement: The circumstance when a client leaves a residential treatment facility without staff's knowledge and consent.

1.23 Facility: The physical plant where services are offered.

1.24 Fee Schedule: A document that provides a list and an explanation of fees for services available from the service provider.

1.25 Federal Confidentiality Regulations: Rules and regulations regarding Confidentiality of Alcohol and Drug Abuse Client Records, 42 CFR Chapter 1, Subchapter A, Part 2, et seq., dated 1986, and final rules thereof.

1.26 Follow-up Treatment: Treatment offered as an extension to residential and nonresidential rehabilitation programs to provide individual or group counseling services to clients following completion of the intensive phase of the treatment program.

1.27 Full License/Certificate: A license/certificate issued when an applicant is in substantial compliance with these regulations.

1.28 Human Subject Research: The use of clients or their treatment records in the systematic study, observation, or evaluation of factors related to the prevention, assessment, treatment, and understanding of an illness.

1.29 Indicators: Measurable or definable items that can be used to demonstrate change, written in measurable and behavioral terms. The indicators are a required part of the treatment plan.

1.30 Intake: The process of collecting demographic and clinical data required for admission to a treatment program.

1.31 Intensive Outpatient Program (IOP): A comprehensive program of substance abuse evaluation, diagnosis and treatment services in a setting that does not include an overnight stay, providing a short-term, structured treatment experience for persons who do not require a more restrictive, residential setting for effective treatment.

1.32 Investigation (Licensing): A review of policies, record keeping, and interviews by the Licensing Authority to determine an agency's or individual's appropriateness of responses in a situation from which a complaint has been generated to determine compliance with licensing regulations.

1.33 License/Certificate: Authorization by DHHS to operate a substance abuse program in the State of Maine.

1.34 Licensee: Any individual, partnership, corporation, association, or organization that has been granted a license/certificate to operate a substance abuse program or service. Licensee is also known as a Provider.

1.35 Licensing Authority: DHHS, Division of Licensing and Regulatory Services, Community Services Programs.

1.36 Licensing/Certificate Review: An on-site review of a program conducted by personnel from the Licensing Authority to determine compliance with regulations.

1.37 May: Verb used to reflect an acceptable method of achieving compliance with these regulations that is recognized but not necessarily preferred or mandatory.

1.38 Medical Assessment: The documentation of the physical condition of a client made by a program in accordance with a protocol established by the medical director.

1.39 Medical Director: A physician (M.D. or D.O), employed by the licensee, with knowledge of substance abuse, addiction, and co-occurring disorder issues.

1.40 Minimally contracted staff: A staff person who works per diem on an infrequent and irregular basis, i.e., no more than six times a year. An example of a minimally contracted staff person is a nurse who works at a residential program one or two weekends a year. (See definition of Affiliate Counselor.)

1.41 Module: A service category found under a licensing component. Outpatient or residential programs are examples of modules in a substance abuse component.

1.42 MRSA: Maine Revised Statutes Annotated.

1.43 Negative Licensing Action: Means a decision by the Licensing Authority or Department as provided by the Maine Administrative Procedures Act, Title 5 M.R.S.A. § 9051 et seq. to deny a license/certificate or issue a conditional license/certificate.

1.44 Non-clinical Staff: Program staff who are not qualified through experience, training, and licensure to provide clinical interventions. Some examples of non-clinical staff include clerical and administrative staff, attendants, and housekeeping staff.

1.45 Nonresidential: Any substance abuse treatment conducted in a setting that does not include, require, or provide that someone stay overnight in lodgings provided by the program.

1.46 Office or OSA: Maine Office of Substance Abuse.

1.47 Outpatient Treatment: Nonresidential services that provide substance abuse evaluations, treatment, and prevention services.

1.48 Physician Extender**.** Physician extender means a nurse practitioner performing duties as defined in 32 M.R.S.A. § 2102 or a physician assistant as referred to in 32 M.R.S.A. § 2594-A.

1.49 Plan of Correction (hereinafter POC): A section of the Statement of Deficiencies completed by the agency, detailing the plan to correct deficiencies and the completion dates.

1.50 Policy: A statement of the principles that guide and govern the activities, procedures, and operations of a program.

1.51 Policy and Procedures Manual: Formal documentation of a program's policies and related procedures required in these regulations, plus additional program policies and procedures that the program wishes to communicate to its staff. (See Policy, and see Procedure.)

1.52 PNMI (Private Non-Medical Institution): A private non-medical institution means a substance abuse treatment program, billing under the MaineCare Benefits Manual, 10-144 CMR c. 101, Ch. II and Ch. III, Section 97, and which meets additional requirements, as outlined herein.

1.53 Procedure: A series of activities designed to implement the goals or policies of a program.

1.54 Program: One or more substance abuse treatment services within an agency, conducted in a residential or nonresidential setting that has a mission, philosophy, and model of treatment designed to address the needs of clients.

1.55 Provisional License/Certificate: A license/certificate issued to a first-time applicant when the applicant is not eligible for a full license/certificate, but the health and well-being of clients are not jeopardized.

1.56 Qualified Service Organization Agreement (QSOA): A written agreement between a treatment program and an outside organization, in compliance with 42 CFR Chapter 1, Subchapter A, Part 2, that allows disclosure of client information without the client's consent. Examples of services covered under a QSOA include data processing, dosage preparation, and accounting services.

1.57 Residential Services: Any substance abuse program that requires the client to reside on the premises while receiving treatment.

1.58 Shall: Verb used to indicate a mandatory procedure, the only acceptable method under these regulations.

1.59 Shelter: A service that provides food, lodging, and clothing, for the purpose of protecting clients, and motivating them to seek substance abuse treatment.

1.60 Should: Verb used to reflect the preferable procedure, yet allowing for the use of effective alternatives.

1.61 Site: The physical location of a substance abuse program.

1.62 Statement of Deficiencies (hereinafter SOD): A document issued by the Department, which describes deficiencies in complying with these regulations.

1.63 Substance Abuse: The use of alcohol and other drugs, licit or illicit, which results in an individual's physical, mental, emotional, or social impairment.

1.64 Substance Abuse Program: A public or private establishment, organization, or institution that offers, maintains, or operates one or more treatment services for the assessment, diagnosis, treatment, or rehabilitation of individuals who are suffering physically, emotionally, or psychologically from the abuse of alcohol or other drugs.

1.65 Substance Abuse Treatment Service: A specific ongoing module of treatment provided by an agency as prescribed in Section 19 of these rules.

1.66 Supportive Services: Additional services that assist the client to derive the maximum benefit from the program’s primary services.

1.67 Training: Special schools, in-service programs, workshops, and other structured opportunities for staff intended to:

1.67.1 Improve administration of programs;

1.67.2 Develop skills in treating substance abusers and their families;

1.67.3 Increase knowledge, skills and abilities related to drug abuse, alcohol abuse, addiction, and the special populations served.

1.68 Treatment: The broad range of substance abuse interventions, designed to positively influence the behavior of clients toward identified treatment goals and objectives.

1.69 Treatment Plan: A written action plan, based on assessment data, that identifies the clients' clinical needs, the strategy for providing services to meet those needs, treatment goals and objectives, and the criteria for completing specific interventions, written in behavioral terms.

1.70 Volunteer: A person who, without financial compensation, provides services to the program.

1.71 Waiver: The intentional relinquishment of the right to enforce a specific section of these rules, granted to an agency by the Licensing Authority.

2.0 LICENSING PROCEDURE AND REVIEW

2.1 Terms and Types of Licenses/Certificates. Any individual(s), partnership, corporation, association, or organization desiring to operate a substance abuse program shall, prior to operations, obtain a license/certificate from the Office of Substance Abuse, except residential programs operated by hospitals that are currently accredited by the Joint Commission on Accreditation of Healthcare. They will be deemed to have met all the licensure requirements of these regulations. Application for licensure shall be made on forms provided, upon request from the Office. It is expected that the process leading to issuance or denial of a license/certificate will be completed within 90 days of receipt of the completed application packet.

2.1.1 Prohibition. No service governed by these rules may be provided without appropriate licensure/certification.

2.1.2 Licenses/certificates. Licenses/certificates shall not be issued without the identification of at least one component, one module, and one substance abuse treatment service. Licenses/certificates shall be issued to agencies that meet the terms and conditions described in **2.1.2.2**.

2.1.2.1 Provisional License/Certificate.

2.1.2.1.1 A provisional license/certificate shall be issued to an applicant that:

2.1.2.1.1.1 is not currently providing any service governed by these rules or has not operated during the term of that license/certificate, and

2.1.2.1.1.2 complies with these regulations, except those which can only be complied with once clients are served by the applicant; and

2.1.2.1.1.3 demonstrates the ability to comply with these regulations by the end of the provisional term. The provisional license/certificate shall specify what regulations need to be met before the program will be eligible for a full license/certificate.

2.1.2.1.2 The provisional license/certificate shall be issued for a minimum period of 3 months or a longer period, as deemed appropriate by the Licensing Authority. A provisional license/certificate may be extended by the Licensing Authority but may not exceed 12 consecutive months in total length.

2.1.2.2 Full License/Certificate.

2.1.2.2.1 A full license/certificate shall be issued to an applicant that complies with all applicable laws and rules.

2.1.2.2.2 A full agency license/certificate shall be valid for from the date of issuance unless revoked, suspended or made conditional.

2.1.2.3 Conditional License/Certificate.

2.1.2.3.1 A conditional license/certificate may be issued when the agency fails to comply with applicable law and rules, and, in the judgment of the Licensing Authority, the best interest of the public would be served by issuing a conditional license/certificate.

2.1.2.3.2 The conditional license/certificate shall specify when and what corrections must be made during the term of the conditional license/certificate.

2.1.2.3.3 The conditional license/certificate shall extend to cover all services provided under the license/certificate.

2.1.2.3.4 The conditional license/certificate shall be issued for a specific period not to exceed one year, or the remaining term of the previous full or provisional license/certificate, whichever the Licensing Authority determines appropriate based on the laws and rules violated. It may be extended by the Licensing Authority but may not exceed 12 consecutive months in total length.

2.1.3 Components, Modules, Substance Abuse Treatment Services, and Sites

2.1.3.1 Agencies shall operate under one license/certificate. Only the components, modules and substance abuse treatment services specifically approved by the Licensing Authority may be provided and only at sites specifically approved for those services. An additional component, module, substance abuse treatment service, or site may be added to an existing agency license/certificate after submission and approval of a new application with the required policy and procedures, a fire inspection request form, and when an applicant:

2.1.3.1.1 is not currently licensed/certified to provide the service(s) for which application is made;

2.1.3.1.2 complies with all applicable laws and rules;

2.1.3.1.3 is in full compliance with other currently licensed/certified services;

2.1.3.1.4 does not currently have a conditional, revoked, or suspended license/certificate.

2.1.3.2 Substance abuse treatment programs may be eligible to provide evaluation and counseling services to clients referred from the Driver Education Evaluation Programs (DEEP). To provide DEEP services, programs must:

2.1.3.2.1 Comply with a signed LETTER OF AGREEMENT between the Department and treatment program: and

2.1.3.2.2 Attend a mandatory introductory training prior to providing services for DEEP referrals and DEEP specific trainings as required by DEEP and able to show documentation of this to the Licensing Authority.

2.2 Initial Application for an Agency License/Certificate.

2.2.1 Application Form. Initial applications shall be made on a form provided by the Licensing Authority.

2.2.1.1 The initial application for an initial agency license/certificate shall be signed and dated by the presiding officer of the Governing Body.

2.2.1.2 The initial application for an additional component, module, substance abuse treatment service, or site shall be signed and dated by the Chief Administrative Officer. A new application form must be submitted for any new components, modules, substance abuse treatment services, or sites requested.

2.2.1.2.1 Each application to add a component shall indicate the modules under the component for which application is made.

2.2.1.2.2 Within each module for which application is made, the specific services shall be identified.

2.2.1.2.3 The specific site from which each and every service is to be provided must be identified.

2.2.1.3 The initial application for a license/certificate shall be accompanied by documents demonstrating compliance with the licensing rules specific to the service for which application is made, and includes an Assurance of Compliance form for Title VI of the Civil Rights Act of 1964 (42 USC § 2000d, et seq.).

2.2.1.4 The initial applications to provide any service shall be accompanied by a fire marshal request for each site, including directions to the site.

2.2.1.4.1 Any application for a residential service shall also include a floor plan sketch of the proposed service site, with room dimensions clearly noted.

2.2.1.5 Public notice and a public forum must be conducted by the applicant for all Opioid Treatment Programs, and documentation must be submitted with the application. See Title 22 M.R.S.A. Chapter 103-A.

2.2.2 Mid-Cycle Applications. Agencies seeking to add components, modules, substance abuse treatment services, or sites to existing licenses/certificates between periods of review, shall submit an initial application as described in this Section. The Licensing Authority shall review the new components, modules, substance abuse treatment services, and site(s). When approved, a license/certificate indicating the additional component, module, substance abuse treatment services, and site(s) will be issued. The term of the license/certificate shall remain unchanged.

2.2.3 Fees. Any application shall be accompanied by the appropriate fee(s), including mid-cycle applications for additional components, modules, substance abuse treatment services, and site(s).

2.2.4 Fire and Safety Inspections. Upon receipt of the completed application, the Licensing Authority shall require inspections of the physical plant(s) to ensure compliance with appropriate state and local regulations regarding fire and safety.

2.2.4.1 For nonresidential sites, fire and safety inspections conducted by authorized representatives of organized fire departments and code enforcement officers in the municipality in which the applicant service will be provided may be accepted by the Licensing Authority in lieu of inspection by the State Fire Marshall's office. The agency must indicate their intention to exercise this option in the application package. The agency is solely responsible for requesting this inspection and submitting proof of compliance in a timely way.

2.2.4.2 Residential sites must be inspected by a representative of the State Fire Marshall's office. The Licensing Authority will request the inspection.

2.2.4.3 The Licensing Authority shall not issue the license/certificate until appropriately notified of results of inspections, and plans of correction, if necessary, have been submitted and accepted.

2.2.5 Site Visits. A site visit of each service location shall be conducted by representatives of the Licensing Authority before a license/certificate is issued. The site will be evaluated for its appropriateness to provide the services planned.

2.2.6 Waivers. Waivers may be granted under the following terms and conditions:

2.2.6.1 All requests for waivers shall be made at the time of initial or renewal application. Requests shall be made in writing and submitted to the Licensing Authority.

2.2.6.2 Requests for waivers shall be accompanied by documentation providing clear and convincing evidence which demonstrates that the terms of the waiver will comply with the intent of the rule. At the request of the Licensing Authority, expert opinion shall be provided.

2.2.6.3 Waivers granted shall be in writing for a specific period not to exceed the term of the license/certificate. In order for an agency to renew a waiver, the agency must submit a renewal request to the Licensing Authority prior to the expiration of the term of the existing license/certificate.

Waivers granted shall be for a specific period not to exceed the term of the license/certificate. In order for an agency to renew a waiver, the agency must submit a renewal request to the Department prior to the expiration of the term of the existing license/certificate.

2.2.6.4 Violation of the waiver shall be enforceable as rule and subject to actions described in Section 2.6 regarding Sanctions and Corrective Actions.

2.2.6.5 The Department may waive or modify any provision(s) of these regulations as long as the provision is not mandated by state or federal law, federal rules or regulations and does not violate client rights as detailed in Section 18 of these regulations.

2.2.7 Technical Assistance. Technical assistance may be provided by the Licensing Authority to the applicant/licensee, at the request of the applicant/licensee. Technical assistance is not to be misconstrued as legal advice, and shall not be substituted for agencies' advice of counsel.

2.3 Renewal Applications.

2.3.1 General. Agencies seeking to add components, modules, substance abuse treatment services, or sites to existing licenses/certificates at the time of renewal shall submit a renewal application, as described in this section, and include the additional component, module, substance abuse treatment services, or sites for which they are seeking approval. Renewal applications may be made not less than 60 days nor more than 120 days prior to the date of expiration of the current agency license/certificate.

2.3.2 Responsibility of Licensee. The Licensee shall be solely responsible for making timely and complete application for the renewal of licenses/certificates. Failure to do so may result in the refusal to renew the licenses/certificates.

2.3.3 Application form. Renewal applications shall be made on a form provided by the Licensing Authority.

2.3.3.1 The applications shall be signed and dated by the Chief Administrative Officer.

2.3.3.2 The renewal application shall be accompanied by documentation relevant to the provision of services. Such documentation shall include, but is not necessarily limited to:

2.3.3.2.1 additional policies or other similar material;

2.3.3.2.2 a description of any policies or similar material that has been discontinued or suspended;

2.3.3.2.3 any client record forms that have changes;

2.3.3.2.4 new staff roster.

This documentation must be submitted with the renewal application, whether or not previously submitted.

2.3.3.3 The renewal application shall be accompanied by a copy of documentation of audit completion, including information that the audit was done according to GAAP principles, and a report summary. (See Section 4.3.)

2.3.3.4 Requests for waivers of a particular rule or the renewal of a waiver granted under a current license/certificate shall accompany the renewal application.

2.3.3.5 Requests for deemed status, whether currently in force or newly requested, shall accompany the renewal application. The accrediting survey and findings must be included, if not previously submitted.

2.3.3.6 Renewal applications for a full license/certificate following the issuance of a conditional or provisional license/certificate shall be considered for renewal only after review by the Licensing Authority, as there is no extension beyond a year for either a conditional or provisional license/certificate.

2.3.3.7 The renewal application shall be accompanied by the appropriate fee(s). When timely applications for license/certificate renewals are made on full licenses/certificates, the existing license/certificate shall remain in effect until the Licensing Authority takes final action on such applications. The Licensing Authority shall notify the agency in writing of the receipt of its application, within 20 working days of receipt.

2.3.4 Deemed status.

2.3.4.1 Upon request by the provider, DLRS will determine whether compliance with some or all of these licensing regulations is deemed based on a review of the findings of an accepted accreditation body.

2.3.4.1.1 The Licensing Authority may grant deemed status, based on substantial compliance with an accreditation body's requirements, and other relevant facts.

2.3.4.1.2 A provider must be in compliance with licensing regulations not deemed by DLRS, and the provider is subject to review by the Licensing Authority.

2.3.4.1.3 Regardless of whether deemed status has been granted for all or some of these licensing regulations, DLRS may survey for compliance at its discretion.

2.3.4.2 Renewals based on certification or accreditation shall not exceed the usual two-year term of licensure without reapplication.

2.3.4.3 Licensees are solely responsible for submitting timely documentation to the Licensing Authority to demonstrate the granting of certification or accreditation.

2.3.4.3.1 Such documentation must be submitted within five business days of the agency's receipt of the Licensee's certification or accreditation.

2.3.4.3.2 The Licensee shall submit any subsequent correspondence or documentation regarding compliance with areas cited as deficient by the accrediting body.

2.3.4.4 Re-certification or re-accreditation that is granted at the end of the first year of the two year licensure period shall not cause the license/certificate to be automatically extended for the remainder of the accreditation period.

2.3.4.5 Licensees are solely responsible for submitting documentation to demonstrate recertification or re-accreditation to the Licensing Authority within five business days of learning of such re-certification or re-accreditation.

2.3.4.6 Suspension or non-voluntary withdrawal of accreditation or certification shall immediately cause the withdrawal of deemed

status. Licensees shall notify the Licensing Authority within five business days of learning of such suspension or withdrawal.

2.3.4.7 Agencies that voluntarily withdraw from accreditation or certification programs shall notify the Licensing Authority as soon as possible after the decision to withdraw. Under no circumstances may the notification of withdrawal be later than the last day of accreditation. At the discretion of the Licensing Authority, a site visit may be conducted to ensure compliance with these rules.

2.3.4.8 Agencies licensed/certified under deemed status shall be subject to review by the Licensing Authority for compliance with applicable federal and state laws and rules.

2.4 Transfer of Licenses/Certificates. No license/certificate shall be transferable from one Licensee to another, one component or module to another, one location to another or to expand services to additional locations.

2.5 Licensing Authority's Assessment of Provider Compliance.

2.5.1 Visits to Determine Compliance. Any employee authorized by the Licensing Authority shall have the right of entry at any time consistent with usual hours of operation of the agency or service, to inspect the facility. The Licensing Authority may also copy any documents and records required by these rules in order to determine compliance with law and with these rules.

2.5.1.1 The Licensing Authority shall have the ability to meet or speak with any client, in private, for the purpose of investigating a suspected violation of law or rules established by the Department. The client has the right to refuse to meet or speak to the Licensing Authority.

2.5.1.2 The Licensing Authority may enter a facility that it believes is operating without a license/certificate only with the permission of the owner or person in charge or with a search warrant from the District Court authorizing entry and inspection.

2.5.2 Availability of Information. The Licensing Authority shall have access to any information which the agency is required to have under these rules and any information reasonably related to assessment of compliance with these rules.

2.5.3 Review Components. Licensing Reviews consist of, but are not limited to, reviewing Governing Body Board Minutes, Client Grievances (if applicable), Affiliated Service Agreements (if applicable), Policies and Procedures for each program, Client Records for each program (to be selected by Licensing Authority), Staff and Client

interviews for each program reviewed, Fire Drill Logs for each site, Personnel Records for staff in each program reviewed (to be selected by Licensing Authority), Supervision Logs, Annual Evaluations/Quality Assurance Plan, Staff Development Plan, Financial Audit, Professional and Commercial Insurance, ADA Plans of Correction (if applicable), Fee Schedule, Fire Inspection/Health Inspection, and Written Agreement with Medical Director.

2.5.4 Statement of Deficiencies. After inspection, an SOD will be sent to the licensee if the inspection identifies any failure to comply with licensing regulations. The licensee shall complete a Plan of Correction (hereinafter "POC") for each deficiency, sign the plan and submit it to the Department within ten (10) working days of receipt of any SOD. Failure to correct any deficiency or to file an acceptable POC with the Department may lead to the imposition of sanctions or penalties as described in Sections 2.6 of these regulations.

2.6 Sanctions and Corrective Actions. Whenever the Licensing Authority finds that a service governed under these rules is being provided in a manner not in compliance with applicable rules, or an agency is operating in a manner not in compliance with these rules, the Licensing Authority may take certain actions.

2.6.1 Notice. The Licensing Authority shall notify the agency of the need for a license/certificate. If they are providing an unlicensed service and are unaware of the licensing process, they shall be informed that they have access to technical assistance. If the agency refuses to become licensed/certified, the Licensing Authority may initiate legal action, which may include the Department filing a complaint with the District Court in accordance with the Maine Administrative Procedure Act, Title 5 M.R.S.A. Chapter 375.

The Licensing Authority may take action against an agency's license/certificate relative to one or more components, modules, substance abuse treatment services, or sites operated under the agency's license/certificate, to include the issuance of a conditional license/certificate or other remedies as noted here. Consideration of the severity and pervasiveness of the deficiencies, the ability of the administration of the agency to have known or prevented the violations, the degree to which the agency was forthcoming or deceptive in reporting information to the Licensing Authority, and other relevant facts must be identified and outlined in a written report to the agency.

2.6.2 Refusal to Issue or Renew. When an applicant fails to comply with applicable law, rules, and professional code of ethics, the Licensing Authority may refuse to issue or renew the license/certificate, in whole or for specific components, modules, sites or substance abuse treatment services.

2.6.3 Issuance of Conditional License/Certificate. If, at the expiration of a full or provisional license/certificate or during the term of a full or provisional license/certificate the agency fails to comply with applicable law and rules and, in the judgment of the

Licensing Authority, the best interest of the public would be served, the Licensing Authority may issue a conditional license/certificate or change a full license/certificate to a conditional license/certificate.

2.6.4 Voiding a Conditional License/Certificate. Failure by the conditional licensee to meet the conditions specified by the Licensing Authority shall permit the Licensing Authority to void the conditional license/certificate or refuse to issue a full license/certificate. The conditional license/certificate shall be void when the Licensing Authority has delivered in hand or by certified mail a written notice to the Licensee or, if the Licensee cannot be reached for service in hand or by certified mail, has left written notice thereof at the agency.

2.6.5 Amend or Modify a License/Certificate. The department may amend or modify a license/certificate.

2.6.6 Emergency Suspension. Whenever, upon investigation, conditions are found which, in the opinion of the Department, immediately endanger the health or safety of persons living in or attending a facility, the Department may request the District Court for an emergency suspension pursuant to Title 4 M.R.S.A. § 184, subsection 6.

2.6.7 Suspension, Revocation: Any license/certificate issued may be suspended or revoked for violation of applicable law and rules, or for committing, permitting, aiding or abetting any illegal practices in the operation of the program, or for conduct or practices detrimental to the welfare of persons living in or attending the facility, or receiving services. When the Department believes that a license/certificate should be suspended or revoked, it shall file a complaint with the District Court as provided in the Maine Administrative Procedure Act, Title 5 M.R.S.A. Chapter 375.

2.6.8 Health and Safety Hazard. Whenever, upon investigation, conditions are found which, in the opinion of the Department, immediately jeopardize the health or physical safety of persons living in or attending a facility or receiving services from an agency, the Department may revoke, suspend or refuse to renew any license/certificate without hearing for a period not to exceed thirty (30) days, in accordance with Title 5 M.R.S.A. § 10004(3).

2.7 Appeals. Once the Department determines, in a non emergency situation, that an agency is not in compliance with a regulation and has determined that a negative licensing action shall be taken, the agency may avail itself of the following:

2.7.1 Statement of Deficiencies and Negative Licensing Action Determination. Statement of Deficiencies that result in a negative licensing action determination by the Department may be appealed. Statement of Deficiencies that do not result in a negative licensing action determination by the Department cannot be appealed.

2.7.2 Request for Administrative Hearing. Within 10 days of receipt of the notice of the Department's determination that a negative licensing action shall be taken, the agency may file a written request with the Department for an administrative hearing. If the request for hearing is received within this period, the proposed action will not take effect until after the Commissioner's Final Decision.

2.7.3 Failure to Request a Hearing. In the event the agency fails to request a hearing within I0 days of the notice of action, the action will take effect at the expiration of the 10 day period.

2.7.4 Appeal Procedures. An agency aggrieved by a hearing decision issued as a result of the Department's administrative hearing, may file, within 30 days of the notice of the decision, a complaint with the Superior Court as provided in 5 M.R.S.A. § 11002.

3.0 AGENCY ORGANIZATION

3.1 Statement of Ownership.

3.1.1 Authority. The agency shall maintain documentary evidence of its source(s) of authority to provide services. Such evidence will include articles of incorporation, corporate charter or similar documents.

3.1.2 Records. Corporations, partnerships or associations, whether for-profit or not-for-profit, shall maintain records of the names and current addresses of officers and directors, charters, partnership agreements, constitutions, articles of association and by-laws, as applicable.

3.1.3 For Profit Organizations. Organizations operating on a for-profit basis shall maintain the names and current addresses of principal owners.

3.2 Governance.

3.2.1 Definition. There shall be an individual or association of persons (board of directors) with ultimate managerial control and legal responsibility for the operation of the agency, called the Governing Authority.

3.2.1.1 All agencies shall minimally have either:

3.2.1.1 an advisory board which shall

3.2.1.1 include community members and local public officials who reflect diverse perspectives;

3.2.1.2 meet on a regular basis;

3.2.1.3 provide advice to the Governing Authority; and

3.2.1.4 maintain a record of meetings that includes the dates, attendance, and topics discussed.

3.2.1.2 or a board of directors which shall

3.2.1.2.1 include community members who reflect diverse perspectives;

3.2.1.2.2 meet on a regular basis; and

3.2.1.2.3 maintain a record of meetings that includes the dates, attendance, and topics discussed.

3.2.2 Membership of the Governing Authority.

3.2.2.1 Members of the Governing Authority who are assigned responsibilities associated with the licensing of, purchase of services from, or contracting with the agency, or members of the immediate family of such employees shall not be employees of any state or Federal government entity.

3.2.2.2 The agency shall maintain a record of the membership of the Governing Authority, indicating the position and term of office for each member.

3.2.3 Duties of the Governing Authority.

3.2.3.1 Meetings. The Governing Authority shall:

3.2.3.1.1 meet at least quarterly;

3.2.3.1.2 maintain records of attendance and minutes of its meetings. Records of attendance and minutes shall be maintained by the agency and made available to the Licensing Authority;

3.2.3.2 Minutes. Minutes should, at a minimum, reflect board discussions around the treatment services, client satisfaction, and significant fiscal and administrative issues.

3.2.3.2.1 adopt a policy regarding conflicts of interest among its members, that at minimum defines a conflict of interest and a matter of self interest, and the procedures for resolving same.

3.2.3.2.2 Agency Operation and Management. The Governing Authority shall:

3.2.3.2.2.1 develop a mission statement describing the overall philosophy and function of the agency;

3.2.3.2.2.2 be responsible for and have authority over the policies and operations of the agency;

3.2.3.2.2.3 make available to the Licensing Authority any policies or records required by these rules or reasonably related to the assessment of compliance with these rules;

3.2.3.2.2.4 meet with representatives of the Licensing Authority when requested to do so;

3.2.3.2.2.5 ensure that every discrete program, service, facility or other management division is in compliance with the Americans with Disabilities Act (ADA) (42 USC § 12101, et seq.), Section 504 of the Rehabilitation Act (42 USC § 794) and the Maine Human Rights Act (MHRA) (5 M.R.S.A. § 4551, et seq.);

3.2.3.2.2.6 be governed in all respects by the laws, statutes, and regulations of the United States of America and of the State of Maine;

3.2.3.2.3 Fiscal Management. The Governing Authority shall:

3.2.3.2.3.1 ensure that the agency is adequately funded to provide licensed/certified services;

3.2.3.2.3.2 provide physical facilities, staff, equipment, supplies and other needs adequate and sufficient to provide licensed/certified services;

3.2.3.2.3.3 review and approve the agency's annual budget;

3.2.3.2.4 Communication with the Licensing Authority. The Governing Authority shall ensure written notification to the Licensing Authority:

3.2.3.2.4.1 ninety calendar days in advance of any proposed change in location, name or ownership of the agency;

3.2.3.2.4.2 thirty calendar days prior to any planned change or within ten calendar days following any unplanned change of Chief Administrative Officer of the agency;

3.2.3.2.4.3 sixty calendar days in advance of any substantial change in policy or service, including but not limited to the addition of a new service or program;

3.2.3.2.4.4 within two working days after the agency receives notice of any legal proceedings arising from

circumstances related to the provision of services or the continued operation of the facility or program, whether brought against the agency or against any employee;

3.2.3.2.4.5 within two calendar days after receiving notice or learning of criminal convictions for events occurring in the workplace;

3.2.3.2.4.6 within ten calendar days after receiving notice of significant discrepancies found at audit.

3.3 Chief Administrative Officer.

3.3.1 Selection and Appointment.

3.3.1.1 The Chief Administrative Officer, appointed by the Governing Authority, shall be knowledgeable, by training and experience, and capable of managing the affairs of the agency. The CAO shall serve as the administrator of the agency.

3.3.1.2 Nothing in these rules prohibits the Governing Authority from selecting a contracted management company to fulfill the duties of the Chief Administrative Officer, so long as the individual(s) assuming actual duties fulfill those duties in a manner consistent with these rules.

3.3.2 Duties of the Chief Administrative Officer. The Chief Administrative Officer shall:

3.3.2.1 manage the affairs of the agency in accordance with policies established by the Governing Authority and ensure compliance with all rules and regulations applicable to the provision of services and all programs operated by the agency, except those specifically noted to be the responsibility of the Governing Authority;

3.3.2.2 have directional authority over all operations of the agency;

3.3.2.3 ensure written notification to the Licensing Authority and the Office of Substance Abuse within 24 hours of an incident resulting in a death, suicide attempt, serious injury, elopement, or other critical incident, pursuant to 1.18 and 5.2; an allegation of abuse or violation of rights; or any other serious event or occurrence;

3.3.2.4 ensure written notification to the Licensing Authority of arrests or indictments of staff related to drug use or other criminal activity on the grounds of any program or location for the provision of services, within 24 hours of learning of the event;

3.3.2.5 ensure written notification to the Licensing Authority in the event of fire, structural damage or other catastrophe which renders any structure used for the provision of licensed/certified services, unsafe, unusable or uninhabitable, within 24 hours following such event;

3.3.2.6 ensure timely written notification to the Licensing Authority prior to a change of administrator, a closure, or changes in program components, modules, substance abuse treatment services or sites;

3.3.2.7 make timely and complete applications prior to changes in or additions to programs;

3.3.2.8 post current, applicable license/certificate(s) issued under these rules in clearly visible place(s) within each licensed/certified facility or program.

4.0 Fiscal Management.

4.1 Budget. There shall be a formal, annualized line item budget, approved by the Governing Authority, indicating anticipated revenues and expenses for the current fiscal year.

4.1.1 Revenue shall be documented by source.

4.1.2 Expenses shall be categorized by line item, and shall be specific to each discrete program, service, facility or other management division.

4.1.3 Revisions to the budget shall be clearly documented.

4.1.4 Review and approval of the budget by the Governing authority shall be clearly documented, including date of approval.

4.2 Policies. The agency shall maintain written policies regarding the fiscal management of the agency. These shall include, but not necessarily be limited to who is responsible for:

4.2.1 purchasing and inventory;

4.2.2 accounts receivable;

4.2.3 accounts payable;

4.2.4 setting of fees or charges for services;

4.2.5 notification to clients of fee schedules and means to document such notification.

4.3 Audits. The agency shall have an annual audit or review of financial operation of overall agency operation and of each discrete program, service, facility or other management division, which shall conform to the requirements of General Audit and Accounting Principles (GAAP), or an inspection specifically approved in writing by OSA, and which shall be conducted by an independent auditor who does not have a conflict of interest, as defined by agency policy.

4.3.1 Audits shall be performed in accordance with applicable state and Federal regulations and shall accurately reflect the agency's financial position.

4.3.2 Audit reports shall be reviewed and accepted by the Governing Authority.

4.3.3 Documentation of such review shall be maintained, including the date of the review. Audit reports and the documentation of review shall be subject to the review of the Licensing Authority.

5.0 Quality Management.

5.1 Quality Assurance Review. There shall be written policies governing the development and maintenance of an effective quality management program.

5.1.1 There shall be a review process to gather input from the Governing Authority, clients, family members, guardians, client advocates, agency staff, funding agencies, members of the community at large, and (when appropriate) the advisory board.

5.1.2 The findings, and actions taken as a result of findings, shall be documented and the plan shall be revised in accordance with the findings.

5.2 Critical Incidents Policies. Specific policies and procedures shall govern the evaluation of critical incidents. Such policies shall include at least the following:

5.2.1 documentation of the event, using the approved Critical Incident Reporting Form. The form is a written document that reflects an occurrence, unusual problem, incident, or deviation from standard practice or situation, that requires follow-up and may require investigation.

5.2.2 a decision tree to evaluate for the need for follow-up actions and opportunities for improvements in program or agency management and service delivery;

5.2.3 documentation of follow-up actions, and timely submission of the approved Critical Incident Reporting Form to the Licensing Authority and the Office of Substance Abuse.

5.3 Reports of Abuse, Neglect or Exploitation. The agency shall maintain a specific policy and procedure governing the reporting, recording and review of allegations of abuse, neglect or exploitation of persons receiving services, in accordance with applicable laws, rules and regulations, including but not necessarily limited to the child and adult protective statutes (22 M.R.S.A. § 4001 et seq., and 22 M.R.S.A. § 3470 et seq.).

5.3.1 The agency must immediately take action to keep clients safe and submit a critical incident report to OSA, according to OSA guidelines.

5.3.2 The policy and procedure shall detail the specific personnel actions to be taken pending the outcome of the investigation and those to be taken at the conclusion of the investigation.

5.4 Grievances. The agency shall maintain a specific policy and procedure governing the reporting of grievances of persons receiving services, the procedural follow-up and response on the part of the agency to the person making the complaint, and the documentation of the process and outcome.

5.4.1 Agencies shall develop the policy in accordance with

5.4.1.1 Section 18.0 of these regulations;

5.4.1.2 State and Federal statutes;

5.1.1.3 Federal rules or regulations.

5.5 Reports of Licensing Violations. The agency shall maintain a specific policy and procedure governing the reporting, recording and review of alleged licensing violations.

6.0 **Insurance.** An insurance program shall be in force at all times. Coverage shall include, but not necessarily be limited to:

6.1 Comprehensive liability insurance for the Governing Authority, personnel, and property, in the amount of $100,000/$300,000;

6.2 Automobile liability insurance for every vehicle owned or operated by the agency, used to transport clients, or vehicles used by staff while conducting agency business.

7.0 Marketing. Marketing and promotional material distributed by or on behalf of the agency shall accurately portray the scope of services provided.

8.0 PERSONNEL MANAGEMENT

8.1 Personnel Policies. The agency shall adopt written personnel policies and procedures to adequately address the following:

8.1.1 Content. Every substance abuse program shall have written personnel policies and procedures that shall, as a minimum:

8.1.1.1 contain a statement of the Code of Ethics under which all employees are expected to operate;

8.1.1.2 contain an affirmative action policy;

8.1.1.3 provide access to an employee assistance plan for all employees;

8.1.1.4 state hours to be worked and provisions for vacation, sick leave, holidays, and fringe benefits, including educational benefits;

8.1.1.5 acquire and retain evidence to demonstrate that all persons engaged in the provision of services regulated by the State of Maine, other applicable government entities, professional associations or similar bodies, are appropriately qualified, certified or licensed ;

8.1.1.6 provide for an annual written performance evaluation of each employee, with the employee's participation;

8.1.1.7 provide a policy for the process of hiring all employees including an administrator;

8.1.1.8 provide a mechanism for disciplinary action and dismissal of an employee;

8.1.1.9 set forth a grievance and appeals procedure;

8.1.1.10 provide access to the personnel policies for all employees (including revisions and updates) at their primary worksite;

8.1.1.11 establish a policy explaining how employees may add information to their personnel record;

8.1.1.12 establish policies requiring employees to provide evidence that they are free of communicable disease, and must consider the limits of inquiry allowed by law (i.e., HIV screening). This information must be the most current report and originate no more than six months prior to hire.

8.1.1.12.1 This information shall be updated minimally every three years.

8.1.1.12.2 Policies concerned with employee health shall be developed with the guidance of the medical director.

8.1.2 Access to personnel policies. Employees and representatives of the Licensing Authority shall have access to personnel policies during regular business hours of the agency.

8.1.2.1 No restrictions of access may be imposed on representatives of the Licensing Authority, nor may fees be charged for copies of personnel policies when access and requests for copies of personnel policies are part of the legitimate functions of the Licensing Authority.

8.1.3 Compensation and Benefits. The agency shall adopt policies and procedures that describe the methods of establishing compensation used by the agency. At minimum, the policy shall address paid and unpaid vacation or other time off, sick leave, leaves of absence, health insurance, educational benefits, retirement, and deferred compensation plans.

8.2 Personnel Records.

8.2.1 General requirement. Personnel records shall be maintained for all staff employed by the agency, contracted staff, volunteers, students, and medical director.

8.2.2 Security. Personnel files shall be secured in the same manner as case records.

8.2.2.1 Copies of any sensitive information in a personnel file, i.e., medical information or disciplinary actions, results of appeals, letters of accommodation and supporting medical records, if applicable, must be stored in a separate file.

8.2.2.2 Content for staff and contracted staff employed by the agency. Personnel records for employees shall, at minimum, contain:

8.2.2.2.1 the application for employment and a resume;

8.2.2.2.2 evidence of professional credentials as required;

8.2.2.2.3 annual performance evaluations;

8.2.2.2.4 documentation of employee's starting, transfer, promotion, demotion, and termination dates as relevant;

8.2.2.2.5 descriptions of training programs, including in-service training, attended while employed at the program as relevant;

8.2.2.2.6 letter of hire, or other documentation of employment agreement;

8.2.2.2.7 the results of all background or reference checks;

8.2.2.2.8 current job description; and

8.2.2.2.9 employment agreements, if applicable, including contracts governing the use of contracted employees, consultants, and affiliate counselors.

8.2.2.3 Content for volunteers, students, and minimally contracted staff. Personnel records for volunteers, students, and minimally contracted staff shall, at a minimum, contain:

8.2.2.3.1 evidence of professional credentials as required;

8.2.2.3.2 documentation of employee's starting, transfer, promotion, demotion, and termination dates as relevant;

8.2.2.3.3 descriptions of training programs, including in-service training, attended while employed at the program as relevant;

8.2.2.3.4 the results of all background or reference checks;

8.2.2.3.5 current job description; and

8.2.2.3.6 employment agreements, if applicable, including contracts governing the use of contracted employees, consultants, and affiliate counselors.

9.0 Organizational Structure.

9.1 Staff Credentials. Every substance abuse program shall have a sufficient number of qualified and trained staff to insure the health and safety of the clients and the efficient operation of the program. Staff shall include at least one (1) full time counselor, or the equivalent, licensed/certified or certified by the Board of Alcohol and Drug Counselors (LADC or CADC) or other professionally licensed/certified person (Advanced Practice Registered Nurse with appropriate specialization certification, M.D., D.O., Licensed Clinical Psychologist, LCSW, LCPC, LMFT only) who meets the following educational and experience requirements: One year clinical experience in substance abuse treatment and a minimum of 60 hours of OSA approved alcohol and drug education in the last five (5) years. Minimum total clinical staff required for program licensure shall be no less than 1.5 full-time clinical staff or the equivalent.

9.2 Staff Responsibilities. The professional staff referred to in Section 9.1 shall be responsible for the provision of direct services to clients. The qualified professional staff shall ensure that a full range of formal treatment services is available to each client in conjunction with the structured set of activities routinely provided by the program and in accordance with the individual client's needs.

9.2.1 There shall be a job description for all employees, including part-time personnel, which includes qualifications, responsibilities, and lines of authority.

9.2.2 The program shall document the pattern of staff coverage throughout the treatment day.

9.2.3 Persons who are providing client services under contract or affiliated service agreement to the program shall be covered by the same personnel policies and held to the same standards as agency personnel, unless that person clearly falls under the category of minimally contracted staff (see Comprehensive Definitions and Interpretive Guideline for Sections 13.4, 13.4.1 and 13.4.2).

9.3 Table of Organization. The agency shall maintain a current table of organization.

9.3.1 The table of organization shall clearly describe the functional lines of authority, oversight, management and consultative relationships between each and every position, body, or board depicted in the table of organization.

9.3.1.1 Services provided through contracted relationships shall be so identified on the table of organization.

9.4 Job Descriptions.

9.4.1 Written Job Descriptions. The agency shall develop and revise as needed written job descriptions for all positions within the agency which include minimum qualifications and job responsibilities.

9.4.1.1 A signed copy of the job description shall be included in the employee's personnel file.

9.4.1.2 The agency shall provide a copy of the job description to each employee at the time of hire, promotion, or orientation.

9.5 Access by Managers. The agency shall ensure access to job descriptions within the individual's chain of command to every person who has management or supervisory responsibilities.

10.0 Medical Director.

10.1 The agency shall retain a physician for a sufficient number of hours to take medical responsibility for the program and effectively perform medical duties, including but not limited to:

10.1.1 develop or approve medical assessment forms;

10.1.2 review and sign off on medical portions of case records, when requested;

10.1.3 develop and supervise policies regarding medications;

10.1.4 review and approve the program's policies and procedures for screening for infectious diseases, including HIV, tuberculosis and Hepatitis B and C.

11.0 Clinical Supervisor.

11.1 General requirements.

11.1.1 The agency shall identify a clinical supervisor for each clinical service, and shall maintain policies and procedures governing the responsibilities of clinical supervisors. There is no requirement for supervision of the medical director or any individual licensed as a physician. The policies shall include, but not necessarily be limited to policies regarding:

11.1.1.1 routine clinical supervision of each clinician or staff member providing clinical services.

11.1.2 Supervision must be conducted at regularly scheduled times.

11.1.2.1 There must be at least one hour of supervision every week for clinical staff who provide at least 20 hours of direct services a week.

11.1.2.2 There must be at least one hour of supervision every two weeks for clinical staff who provide less than 20 hours of direct services a week.

11.1.3 Supervision may be conducted on an individual or group basis, or a combination of both.

11.1.3.1 Individual supervision must be provided at least one quarter of the time.

11.1.3.2 Group size shall include no more than 12 supervisees, unless a plan is submitted by the program and approved by OSA.

11.1.3.3 Supervision time shall be documented in hours, and shall be subject to the review of the Licensing Authority.

11.1.4 Supervision shall include the following:

11.1.4.1 review of case records;

11.1.4.2 documentation in the case records, indicating the occurrence of the review;

11.1.4.3 review of the Case Management substance abuse core function, including adequacy and completeness of screenings, assessments, referrals, etc.;

11.1.4.4 participation in the development of the employee's individual, group and family counseling skills, as applicable;

11.1.4.5 education for clinicians and staff members about clinical issues and treatment modalities;

11.1.4.5.1 Supervision hours cannot be doubly counted toward the twenty hours of required training referred to in Section 13.4.6.3.

11.1.4.6 the maintenance of a record of supervision, including the dates, employees supervised, duration and content of supervision, signed by the supervisor;

11.1.4.7 issues germane to the duties being performed;

11.1.4.8 review of new policies with the supervisees.

11.1.5 day-to-day supervision and evaluation of clinicians and staff members.

11.2 Credential. All clinical supervisors must be credentialed as Certified Clinical Supervisors by the Maine State Board of Alcohol and Drug Abuse Counselors.

12.0 Reference and Background Checks.

12.1 The agency shall conduct background checks on all prospective employees, persons contracted or hired, consultants, volunteers, and students. This shall include, but not necessarily be limited to, background checks through the State Bureau of Investigation, Child Protective Services, Adult Protective Services, Institutional Abuse Unit, the Certified Nursing Assistant register and other similar registers, the Bureau of Motor Vehicles, and such other relevant and available registers, sources of information or data bases.

12.1.1 Such background checks shall be conducted at the agency's expense.

12.1.2 The agency shall not hire any person who has a prior criminal conviction or disciplinary action by a professional licensing, registration or accrediting body that pertains to client abuse or exploitation. See Title 5 M.R.S.A. § 5301 et seq.

12.1.3 In the case of an Adult or Child Protective Services or Institutional Abuse Unit investigation substantiating abuse, neglect, or exploitation by an employee of the agency, it is the agency's responsibility to decide what personnel action to take in response to said report, in accordance with licensing standards.

12.1.4 When the operation of a motor vehicle is expected or reasonably anticipated in the course of an employee, volunteer, or student's work, the agency shall conduct a check of the driving record. The agency shall not permit an employee, volunteer, or student to transport clients if they have a conviction for operating under the influence or any other accident or violation that indicates an unsafe driving history within the past three (3) years.

12.1.5 The agency shall acquire and retain evidence that all persons who in the completion of their duties are required or could be reasonably anticipated to operate a motor vehicle, have valid driver's license appropriate to the class of vehicle to be used. If a staff person, in the course of work, is operating a vehicle not provided by the agency, evidence of registration, inspection, and insurance shall be maintained. Such evidence shall be acquired at the commencement of the person's employment and shall be maintained and reviewed periodically.

12.1.6 Employment of any individual shall be contingent upon results of the background checks. Background checks must be completed

before the employee has any client contact without another individual present.

12.1.7 If a positive check is discovered, the agency must have a policy and procedure on how this will be addressed

13.0 Direct Care Contracted Staff (Affiliate Counselors).

13.1 An agency utilizing contracted staff to provide counseling services through an affiliated agreement shall require affiliate counselors to fulfill the same requirements in these regulations as non-contracted clinical staff.

13.1.1 The agency shall maintain a full personnel record on affiliate counselors.

13.1.2 The agency shall provide clinical supervision to affiliate counselors according to the same standards set forth in regulation for non-contracted clinical staff.

13.1.3 All affiliate counselors must inform clients of their affiliation with the agency through signage, marketing, and communication technologies.

13.2 Volunteers.

13.2.1 Policies. Agencies engaging volunteers shall adopt and follow policies and procedures for their identification, supervision, orientation and use.

13.2.2 Criteria. Agencies utilizing volunteers who have direct contact with individuals receiving services or who have access to confidential client information shall ensure that volunteers are trained in the specific job responsibilities related to their position, and receive position-related orientation in all areas referred to in Section 13.4.

13.3 Students.

13.3.1 Policies. Agencies providing or participating in the provision of experiential education for students shall adopt and follow policies and procedures for their identification, supervision, orientation and use, including:

13.3.1.1 a description of the purpose of the student's involvement;

13.3.1.2 the student's roles and responsibilities;

13.3.1.3 a description of orientation procedures and training procedures;

13.3.1.4 the student's required minimum qualifications;

13.3.1.5 the designation of a liaison between the agency and the school making such placements.

13.3.2 Criteria. Agencies providing or participating in the provision of experiential education for students resulting in direct contact with individuals receiving services or access to confidential client information shall ensure that students meet the same training and orientation criteria as employees, as described in Section 13.4.

13.3.2.1 Students shall not provide therapy services for the agency unless they are:

13.3.2.1.1 enrolled in a master's program or above; and

13.3.2.1.2 approved for the practicum by the college/university practicum placement supervisor.

13.3.2.2 Students must be under the close supervision of a certified clinical supervisor, working for the agency, who, along with the practicum placement supervisor, shall accept responsibility for supervision of the clinical services provided by the student.

13.4 Training and Orientation.

13.4.1 General Orientation Program. The agency shall provide orientation relevant to the organization to new employees, students, and volunteers. The orientation shall include, but not be limited to:

13.4.1.1 the agency's mission, philosophy, and description of services;

13.4.1.2 the clients' rights regarding privacy and confidentiality;

13.4.1.3 rights of clients applicable to services provided;

13.4.1.4 safety and emergency procedures;

13.4.1.5 review of the agency's policy on physical intervention.

13.4.2 Position-Specific Orientation and Training. The agency shall provide orientation and training specific to the duties for which an employee is responsible to new employees, students, volunteers, and promoted or transferred employees. This orientation and training shall include, but not necessarily be limited to:

13.4.2.1 specific job responsibilities. For persons in managerial or supervisory positions, this shall include responsibilities and procedures for management, supervision, and discipline of employees;

13.4.2.2 safety and emergency procedures particular to the type of work, the location of the work and the persons being served;

13.4.2.3 infection control and prevention, particular to the type of work, the location of the work, and the persons being served;

13.4.2.4 specialized techniques of communication and intervention, as applicable to the needs of the persons being served;

13.4.2.5 training in the interrelationship of co-occurring conditions, referral and treatment processes;

13.4.2.6 assessment, treatment planning, treatment delivery, and documentation appropriate to the position and to the persons served in the program.

Interpretive Guideline for 13.4, 13.4.1 and 13.4.2

For staff who are minimally contracted, working per diem (e.g., a nurse working one or two weekends a year), written information may be developed that can be provided to the employee, in lieu of a comprehensive orientation, that covers general program information and position-specific orientation applicable to a minimally contracted employee. The agency must have a policy that clearly states what the requirements are for a minimally contracted employee. This designation would not be appropriate for positions that might work on a regular basis, such as an affiliate counselor.

13.4.3 Assumption of duties following orientation. Employees, volunteers, and students shall not be assigned to duties requiring direct involvement with clients until the position-specific orientation, and the general orientation regarding the reporting of abuse and neglect, safety and emergency procedures, client rights, and confidentiality have been completed and documented.

13.4.3.1 The remaining training and orientation elements must be completed within 60 calendar days of hire.

13.4.4 Contracted positions or affiliate counselors. Persons contracted to provide direct services to clients on behalf of the agency shall complete orientation as described in these rules, or the agency shall provide evidence, subject to the review and approval of the Licensing Authority, of equivalent training.

13.4.5 Consultants. The agency shall maintain policies and procedures governing orientation of consultants consistent with the services provided by the agency, the needs of persons receiving services, and the particular skills and duties of consultants, subject to the review and approval of the Licensing Authority.

13.4.6 Ongoing training and education for clinical staff. The agency shall develop and implement policies and procedures to:

13.4.6.1 ensure compliance with on-going professional training requirements for all licensed, certified, or registered employees;

13.4.6.2 provide staff training needs, pertinent to the services provided by the agency and the staff member;

13.4.6.3 provide no less than 20 hours of annual in-service or external training to all clinicians, which may be prorated for part-time clinicians.

13.4.7 Ongoing training and education for support staff, volunteers, and students. The agency shall develop and implement a job-specific training plan for each individual, to be reviewed and updated annually.

13.4.8 Records of completion of orientation and training. The agency shall maintain written, accessible documentation that orientation and ongoing training have been completed as described in these rules. Such documentation shall include, at a minimum, curriculum, names and credentials of persons providing orientation or training, dates orientation or training was provided, and the length of time of each orientation or training session.

14.0 Administrative Management.

14.1 Lines of Authority. The agency shall maintain policies and procedures governing the application of the lines of authority, as described in the table of organization. This shall include, but not necessarily be limited to:

14.1.1 the passing of responsibility for oversight and supervision from work shift to work shift, or from service delivery site to service delivery site, as appropriate;

14.1.2 the passing of responsibility for oversight and supervision of programs, services, facilities or other discrete service elements, in the temporary absence of the primary supervisor or manager;

14.1.3 the passing of responsibility for oversight and supervision of the agency as a whole, in the temporary absence of the Chief Administrative Officer.

14.2 Management of Programs, Services, Facilities or Other Management Divisions. The agency shall maintain policies and procedures governing the selection, supervision and oversight of managers of each discrete program, service, facility or other management division. These shall include, but not necessarily be limited to:

14.2.1 the selection criteria used to name a manager of each program, service, facility or other management divisions;

14.2.2 the supervisory chain of command within which the manager of each program, service, facility or other management division is provided oversight, supervision and guidance;

14.2.3 the supervisory chain of command for every position within each program, service, facility or other management division, reporting to the manager.

14.3 Evaluations of performance. The agency shall maintain policies and procedures governing the routine, periodic, formal evaluation of the performance of employees. Such policies shall include, but not be limited to:

14.3.1 procedures for employee evaluations;

14.3.2 the development and implementation of individualized performance improvement and training plans;

14.3.3 frequency of evaluations, which shall be completed no less frequently than at the conclusion of the first six months of employment, and annually thereafter, whether full or part time;

14.3.4 documentation of evaluations;

14.3.5 provision of copies of evaluations to employees.

14.4 Discipline. The agency shall maintain policies and procedures governing employee discipline.

14.4.1 Such policies shall include, but not be limited to:

14.4.1.1 the circumstances under which discipline may be administered;

14.4.1.2 the range of interventions or penalties permitted;

14.4.1.3 the circumstances under which particular penalties are required or permitted;

14.4.1.4 procedures for employees' appeal of discipline;

14.4.1.5 documentation of disciplinary actions and results of appeals.

14.4.2 Policies for employee behavior that are subject to discipline shall include, but not necessarily be limited to:

14.4.2.1 the penalties for client abuse, mistreatment, neglect or exploitation;

14.4.2.2 the penalties for violation of client rights;

14.4.2.3 the penalties for violation of rules of confidentiality, including those specific to the services being provided;

14.4.2.4 the penalties for workplace use or possession of illicit substances, alcohol or firearms;

14.4.2.5 the penalties for working under the influence of illicit substances or alcohol;

14.4.2.5.1 There shall be a policy and procedure for appropriate employee assistance

intervention when the employee is self-reporting a substance abuse problem.

14.4.2.6 how the agency will address allegations of illicit substance use or abuse of alcohol by an employee;

14.4.2.7 the penalties for falsification of any documents related to hiring or retaining of employees, whether for self or on behalf of others;

14.4.2.8 the penalties for violation of personnel laws (including but not necessarily limited to EEO and ADA) and agency personnel policies.

14.5 Employee Grievances. The agency shall maintain policies and procedures governing the filing, processing, and resolution of grievances brought by employees as a result of management practices.

15.0 OPERATIONAL PRACTICES

15.1 Administration of Services.

15.1.1 Service Descriptions. Each program shall be specifically named and described in policy.

15.1.2 Subcontracted services. When an agency or program offers services through another provider, a documented cooperative, affiliated service or subcontracting agreement shall exist. This agreement shall be updated as changes occur. The agency shall ensure that services provided through an affiliation agreement or subcontract comply with these rules and any contractual requirements.

15.1.3 Program Manager. The agency shall designate an individual as program manager, having overall responsibility for the operation of each program.

15.1.3.1 the duties of the program manager shall be clearly described in the written job description, including minimum qualifications, responsibilities and lines of authority.

15.1.3.2 nothing in these rules prohibits the sharing of managers between programs, if the programs are adequately managed.

15.1.4 Population Served. Characteristics of the population served shall be specifically defined for each program.

15.1.5 Reporting requirements. Agencies licensed/certified to provide substance abuse treatment shall submit such data as may be required by the Office of Substance Abuse, in the form and format specified, and within time frames requested.

15.2 Provision of Services to Clients.

15.2.1 Case Records. A case record shall be maintained for each client. Each program shall describe the format and content for records in the program policy and procedure manual.

15.2.1.1 The client record describes the client's health status at the time of admission, the services provided and the client's

progress in the program, and the client's health status at the time of discharge.

15.2.1.2 The client record shall provide information for the review and evaluation of the treatment provided to the client.

15.2.2 All programs shall be in compliance with Federal Confidentiality Regulations as outlined in 42 CFR Chapter 1, Subchapter A, Part 2, et seq. and amendments thereof.

15.2.2.1 Case records shall be maintained in a secure room, locked file cabinet, safe, or other similar container when not in use.

15.2.2.2 There shall be a written plan describing methods and procedures used to ensure confidentiality of case records.

15.2.2.3 There shall be a written plan to address security of active and inactive records, including access and removal from storage.

15.2.2.4 There shall be a written plan for disposition of client records in compliance with Federal Confidentiality Regulations in case of program closure.

15.2.2.5 Case records shall be preserved for a minimum of 6 years except in the case of a minor, where they shall be kept for 6 years following the client's 18th birthday.

15.2.2.6 Upon admission, all clients shall be provided with a written summary of client rights regarding confidentiality, as described in 42 CFR Chapter 1, Subchapter A, Part 2, et seq. and documented in the case record.

15.2.2.7 There shall be a plan for back-up of automated record systems, if used.

15.3 The case record shall include but not be limited to:

15.3.1 identification data, including name, address, telephone number, and date of birth;

15.3.2 reports from referring sources;

15.3.3 results of the client’s clinical assessment;

15.3.4 a statement signed by the client declaring his/her knowledge of the fee schedule, program rules, expectations, and client rights;

15.3.5 updated treatment plans and treatment plan reviews;

15.3.6 progress notes, which must be related to specific problems or goals on the treatment plan and serving as the basis for evaluating treatment outcomes. This shall include but not be limited to the following:

15.3.6.1 documentation of implementation of the treatment plan;

15.3.6.2 documentation of all treatment rendered to the client;

15.3.6.3 descriptions of changes in the client's conditions, his/her response to treatment, and, as appropriate, the response of significant others to his/her treatment;

15.3.6.4 the date, signature, and professional qualifications of the individual making the entry in the case record.

15.3.7 Each closed case record shall also contain:

15.3.7.1 a discharge summary which describes the client's course of treatment, program completion status, and the client's condition at discharge. The discharge summary shall make reference to the client's progress toward planned goals as listed on the treatment plan;

15.3.7.2 a treatment follow-up plan (See Section 15.9).

15.3.7.3 Whenever appropriate to the client's treatment the case record shall additionally include, but not be limited to:

15.3.7.3.1 family assessment as part of the process leading to the development of the individual treatment plan;

15.3.7.3.2 correspondence pertinent to the case;

15.3.7.3.3 signed consent forms for release of information, which must comply with Federal Confidentiality Regulations, and which, at a minimum must specify:

15.3.7.3.3.1 the entities from which and to which information is provided;

15.3.7.3.3.2 the purpose for which the information is requested, which must be related to treatment;

15.3.7.3.3.3 the scope and content of information requested (such as medical records, work records, etc.);

15.3.7.3.3.4 the period during which the release is valid. The period shall not exceed 365 consecutive calendar days;

15.3.7.3.3.5 the acquisition of dated signatures from parents of children or guardians when one has been appointed if the child lacks capacity because of extreme youth, or mental or physical incapacity, as per 42 CFR Chapter 1, Subchapter A, Part 2, et seq.;

15.3.7.3.3.6 the mechanism to withdraw consent for the release of information;

15.3.7.3.3.7 prohibition on re-release statement.

15.3.7.3.4 referrals for service to other agencies, including reasons for referral.

15.3.7.3.5 Program policies will include a plan to ensure legibility and integrity of entries to records. At a minimum, the policy must address:

15.3.7.3.5.1 corrections to records, prohibiting the use of correction fluid, tapes, labels

and similar techniques and devices;

15.3.7.3.5.2 the prohibition of back-dating entries;

15.3.7.3.5.3 a provision for the use of late entries to records, which must include the use of a phrase identifying the entry as late;

15.3.7.3.5.4 a requirement for an easily recognizable date for every entry;

15.3.7.3.5.5 signatures and identification of persons making entries to records, including professional credentials.

15.4 Admission Policies.

15.4.1 Every program shall have written admission policies and procedures that shall include:

15.4.1.1 criteria for determining the eligibility of individuals for admission;

15.4.1.2 provision for an assessment that concludes that the treatment required by the client is appropriate to the level and restrictions of care provided by the program components, and that the treatment can be appropriately provided by the program;

15.4.1.3 procedures to make clients aware of program philosophies and rules and regulations;

15.4.1.4 a fee schedule, which shall be fully explained upon admission;

15.4.1.5 procedures to ensure that those clients refused treatment shall be informed of reasons for denial and a record is maintained of those refusals and reasons.

15.4.2 There shall be written policies delineating conditions for re-admission and for denial of same, which shall ensure that persons shall not be denied re-admission solely because they:

15.4.2.1 have withdrawn from treatment against clinical advice on a prior occasion;

15.4.2.2 have relapsed from earlier treatment.

15.4.3 There shall be a written procedure for clients who wish to appeal any adverse judgments on admission.

15.4.4 Waiting Lists. All treatment programs must maintain a log or register listing individuals actively seeking treatment whenever a program's service capacity has been reached. If such a listing is needed, it must be monitored. Individuals are appropriately placed on a waiting list when they meet screening and eligibility criteria for services of the program.

15.4.4.1 If required as defined above, waiting list procedures shall:

15.4.4.1.1 assure individuals are screened and referred or prioritized for admission according to a consistently applied needs criteria;

15.4.4.1.2 document the treatment requested and needs presented by the individual;

15.4.4.1.3 identify service needs of individuals based on available data;

15.4.4.1.4 identify and note referrals made matching the individual's needs to appropriate community resources;

15.4.4.1.5 be described in a program's written waiting list procedures.

15.5 Referral of Clients.

15.5.1 The program shall have written policies and procedures to facilitate client referral and plans for coordinating the services with other agencies, if applicable:

15.5.1.1 between the program's service components;

15.5.1.2 between the program and other community service providers.

15.5.2 Procedures shall be established to ensure completion of the referral process under the following conditions:

15.5.2.1 when a client is deemed inappropriate for admission to the program but is still in need of care;

15.5.2.2 when the client is in need of examinations, assessments, and consultations which are not within the professional domain or expertise of the staff;

15.5.2.3 when the client is in need of special treatment services.

15.5.3 There shall be written policies and procedures for monitoring the prioritization of the agency waiting list(s) and the referral process to other treatment programs and services.

15.5.4 Program staff shall screen clients for unmet medical and mental health needs and complement the substance abuse plan of care with appropriate referrals for this care.

15.6 Clinical Assessment.

15.6.1 For each client there shall be a complete assessment that concludes that the treatment required by the client is appropriate to the level and restrictions of care provided by the program component, and that the treatment can be appropriately provided by the program. An initial assessment must be completed prior to development of the treatment plan.

15.6.2 The assessment shall include, but is not limited to:

15.6.2.1 History of alcohol and drug use, including:

15.6.2.1.1 age of onset

15.6.2.1.2 duration

15.6.2.1.3 patterns

15.6.2.1.4 consequences

15.6.2.1.5 family usage

15.6.2.1.6 types of previous treatment

15.6.2.1.7 response to previous treatment

15.6.2.2 History, strengths, and needs in the following categories, including the clinician's and client's perceptions:

15.6.2.2.1 physical health

15.6.2.2.2 medication

15.6.2.2.3 allergies

15.6.2.2.4 nutritional

15.6.2.2.5 emotional

15.6.2.2.6 psychological

15.6.2.2.7 crisis intervention needs

15.6.2.2.8 family history

15.6.2.2.9 current home situation

15.6.2.2.10 physical, emotional, sexual, and domestic abuse

15.6.2.2.11 social supports

15.6.2.2.12 legal

15.6.2.2.13 financial

15.6.2.2.14 housing

15.6.2.2.15 vocational

15.6.2.2.16 educational

15.6.2.2.17 leisure and recreational interests

15.6.2.2.18 spirituality and religion

15.6.2.2.19 military

15.6.2.3 Assessments, and any addenda to assessments, should also include:

15.6.2.3.1 a summary;

15.6.2.3.2 an evaluation of the information;

15.6.2.3.3 documentation of previous diagnoses, if appropriate, and current substance abuse diagnosis;

15.6.2.3.4 signature and credentials of assessor and date signed.

15.7 Individual Treatment Plan.

15.7.1 An individually written treatment plan shall be maintained for each client.

15.7.2 The plan shall be based on a comprehensive assessment of the client's needs, which includes, but is not limited to information gathered in an assessment, as listed above.

15.7.3 An initial treatment plan shall be developed within 72 hours following admission to any residential program, or within 3 sessions following admission to an outpatient program or IOP.

15.7.3.1 A comprehensive treatment plan, updating the initial treatment plan, shall be completed according to the schedule in 15.7.5.3 below.

15.7.4 Comprehensive treatment plans must contain the following elements:

15.7.4.1 problems to be addressed during treatment;

15.7.4.2 measurable long-term treatment goals that relate to problems identified in the assessment;

15.7.4.3 measurable short-term goals leading to the completion of the long-term goals;

15.7.4.3.1 time frames for the anticipated dates of achievement/completion of each goal, or for reviewing progress toward goals.

15.7.4.3.2 specification and description of the indicators used to assess the individual's progress.

15.7.4.3.3 the treatment procedures proposed to assist the client in achieving these goals, including:

15.7.4.3.3.1 type and frequency of services to be provided.

15.7.4.3.3.2 referrals for needed services that are not provided directly by the program.

15.7.4.4 documentation of participation by the client in the treatment planning process, as evidenced by the client's signature on the treatment plan, or the reason why the client did not participate;

15.7.4.5 a description of any tests ordered and/or performed by the program and the results;

15.7.4.6 the clinician's signature, dated, with the clinician's credentials noted.

15.7.5 The treatment plan shall be reviewed and updated during the course of treatment.

15.7.5.1 This review shall:

15.7.5.1.1 document the degree to which the client is meeting his/her treatment goals;

15.7.5.1.2 modify existing goals or establish new ones as necessary.

15.7.5.2 The updated plan shall be signed by counselor and client at time of review.

15.7.5.3 The plan shall be reviewed at least:

15.7.5.3.1 every week in a program of 30 days duration or less (detoxification, brief residential, and IOP);

15.7.5.3.2 every month for programs of 31 to 180 days (Category I and Category II programs, as defined in Section 19.)

15.7.5.3.3 every 3 months for programs in excess of 180 days (Category III programs, as defined in Section 19);

15.7.5.3.4 every 3 months of outpatient treatment.

15.8 Discharge Policies and Procedures.

15.8.1 Every program shall have written discharge policies and procedures. These shall include:

15.8.1.1 procedures for planning the client's discharge in consultation with the client when one of the following conditions are met:

15.8.1.1.1 it is evident to staff that the client has received optimum benefit from treatment and further progress requires either the client's return to the community or the client's referral to another type of treatment program;

15.8.1.1.2 the client has achieved the indicators of the treatment plan that reflect the critical goal of treatment which may be one or more of the following:

15.8.1.1.2.1 medical stability,

15.8.1.1.2.2 recognition and understanding of the substance abuse problem,

15.8.1.1.2.3 development of skills to enable him or her to increase life functioning and reduce the risk of relapse;

15.8.1.1.3 policies and procedures to be followed for discharge in the event that a client leaves the program against medical advice or has been administratively discharged from the program;

15.8.1.1.4 a requirement that the administrator (or designee) shall refer the person to another facility/program for treatment when appropriate;

15.8.1.1.5 procedures to encourage the client to agree to follow-up care after discharge;

15.8.1.1.6 a statement describing indicators to be used in determining successful program completion;

15.8.1.1.7 procedures for ensuring that clients who require assistance in obtaining supportive services or additional care shall have assistance from the program staff in making arrangements;

15.8.1.1.8 a statement that the staff shall make reasonable provisions for transportation to another facility/program, or to the client's home, even if the client leaves against clinical advice or receives an administrative discharge;

15.8.1.1.9 procedures to assist clients in obtaining shelter when needed.

15.8.2 Each program shall establish a written procedure for clients who wish to appeal any adverse judgments on program discharge.

15.9 Treatment Follow-up.

15.9.1 Programs shall develop written follow-up plans for all clients who are discharged from the treatment program.

15.9.1.1 The plan shall describe the program's responsibility for facilitating the transfer of the client to follow-up treatment services, other identified professional services, or a client support system.

15.9.1.2 The plan shall be in accordance with the client's reassessed needs at the time of discharge or transfer.

15.9.1.3 The plan shall be developed with the participation of the client and, where indicated, family, guardians or significant other.

16.0 PNMI.

16.1 Provider agreements. All PNMIs must have a provider agreement that encompasses the MaineCare Provider Supplier Agreement on file with the Department of Health and Human Services, Division of Licensing and Regulatory Services, Medical Facilities Unit. Providers must also contract with the Department and satisfactorily meet all contract and provider agreement provisions.

16.2 Compliance with regulations. A PNMI providing substance abuse services shall comply with all portions of these regulations in Section 16 (Substance Abuse Treatment Services) pertaining to the component, module, substance abuse treatment services, and sites offered by the PNMI.

16.3 Coordination of PNMI services. It is the responsibility of the PNMI provider to coordinate PNMI services with other "in-home" services to address the full range of member needs. Other MaineCare covered services shall not duplicate PNMI services included in the facility's PNMI rate. Services that are part of the PNMI rate may not be billed to MaineCare separately by other providers. For example, if the PNMI provides personal care services, and a member receives Home and Community Based Waiver Services, the personal care services shall be delivered by the PNMI provider and not by a certified nursing assistant (CNA), home health aide (HHA), or personal care assistant (PCA) as otherwise allowed.

16.4 Personal care staff and services. PNMIs approved and funded by OSA in licensed/certified facilities may also provide personal care services necessary for the promotion of ongoing treatment and recovery.

16.4.1 The personal care services provided by the PNMI are prescribed by a physician upon or within thirty (30) days of admission, are in accordance with the member's plan of care, are supervised by a registered nurse at least every ninety (90) days, and are not provided by a member of the client's family as described in the MaineCare Benefits Manual, Chapter II, Section 97.01-6 or the pertinent Appendix of the MaineCare Benefits Manual, Chapter III, Principles of Reimbursement.

16.4.2 Alcohol and drug treatment PNMIs that provide personal care services shall maintain documentation that each staff member providing such services has received forty (40) hours of orientation and training in personal care procedures appropriate to residents. Areas of training must include introduction to chemical addictions, assistance in self administration of medicine, infection control, bowel and bladder care,

nutrition, methods of moving clients, and health oriented record keeping.

16.4.3 Personal care services shall consist of, but are not limited to, the following:

16.4.3.1 assistance or supervision of activities of daily living that could include bathing, dressing, eating, toileting, ambulation, personal hygiene activities, grooming, and the performance of incidental household tasks essential to the activities of daily living and to the maintenance of the member's health and safety within the substance abuse treatment PNMI;

16.4.3.2 supervision of or assistance with administration of physician ordered medication;

16.4.3.3 personal supervision or being aware of the member's general whereabouts, observing or monitoring the member while on the premises to ensure their health and safety, reminding the member to carry out activities of daily living, and assisting the member to carry out activities of daily living, and assisting the member in adjusting to the group living facility;

16.4.3.4 arranging transportation and making phone calls for medical or treatment appointments as recommended by medical providers, or as indicated in the member's plan of care;

16.4.3.5 observing and monitoring clients and reporting changes in the client's normal appearance, behavior, or state of health to medical providers or supervisory personnel as appropriate;

16.4.3.6 arranging or providing motivational, diversionary, and behavioral activities which focus on social interaction to reduce isolation or withdrawal and to enhance communication and social skills necessary for ongoing treatment and recovery, as described in the member's plan of care;

16.4.3.7 monitoring and supervising member's participation in the treatment; and

16.4.3.8 psychosocial services including assisting members to adjust to the substance abuse treatment PNMI, to live as independently as possible, to cope with personal problems during periods of stress, to accept and adjust to their personal life situations, to accept and cope with their chemical addictions and to decrease unhealthy behaviors leading to possible relapse into active addiction, in addition to providing services and a supportive environment which promotes feelings of safety and freedom from danger, fear or anxiety.

16.5 Clinical consultant services. Clinical consultant services must be provided by licensed or certified professionals as described in the MaineCare Benefits Manual, Chapter II, Section 97.07-2, who are working within all State and Federal regulations specific to the services provided. For substance abuse facilities, clinical consultants may include substance abuse services including methadone maintenance services.

16.6 Surveillance and Utilization Review Services (SURS). A PNMI is subject to the surveillance and utilization review requirements set out in the MaineCare Benefits Manual, Chapter I.

16.7 Time studies. A PNMI is required to complete all time studies in accordance with the MaineCare Benefits Manual, Chapter II, Section 97.07-8.

17.0 ENVIRONMENT AND SAFETY

17.1 Compliance. The agency shall ensure and document continuous compliance with all applicable laws, rules and regulations governing the location, occupancy, use, maintenance, construction and renovation of physical structures used in the delivery of licensed/certified services.

17.1.1 Evidence. Evidence of compliance shall include, but not necessarily be limited to, approval from local fire departments (if utilized in lieu of inspection by the State Fire Marshall), local boards of zoning and code enforcement, and local health departments, as applicable.

17.1.1.1 The agency shall be required, upon the request of the Licensing Authority, to produce documentation of compliance regarding construction or renovation.

17.1.2 Waivers. Documentation shall include all applicable waivers.

17.2 Structures. All structures used in the delivery of licensed/certified services shall be maintained in good repair and free from danger to health or safety, and shall be appropriate to the services provided.

17.2.1 General.

17.2.1.1 The agency shall meet current requirements of the Americans with Disabilities Act of 1990 (42 USC § 12101, et seq.), the Rehabilitation Act of 1973 (42 USC § 794), and the Maine Human Rights Act (5 M.R.S.A. § 4551, et seq.), including all new construction, renovation, remodeling or repair.

17.2.1.2 The premises shall be free of environmental hazards, including asbestos.

17.2.1.3 Paint which contains lead or products containing asbestos shall not be used for any purpose. All interior lead-based paint or flaking paint must be removed or permanently covered.

17.2.2 Building Interiors.

17.2.2.1 Buildings shall structurally accommodate the services provided therein.

17.2.2.2 Indoor temperatures shall be maintained at a comfortable level, based on the needs of the clients.

Interpretive Guideline for **17.2.2.2**.

This can include use of air conditioning or fans in summer. Special attention should be paid to safety precautions and fire regulations.

17.2.2.3 Administrative and counseling services shall occupy space which is separate and distinct from living areas, when applicable.

Counseling space shall be such that privacy and confidentiality are ensured.

17.2.2.4 Adequate separate space shall be provided for staff whose duties and responsibilities include living-in, sleeping-over, or similar functions. The separation of client and staff sleeping areas shall be absolute.

17.2.2.5 Doors to bedrooms, closets or bathrooms that can be locked must have an emergency release mechanism readily available, that can be activated from both the interior and the exterior of the room or closet.

17.2.2.6 Living rooms, lounges, day rooms or other common areas, when provided, shall accommodate a variety of recreational activities, shall be clean, well lighted, ventilated, and properly equipped.

17.2.2.7 Bathrooms shall be equipped to facilitate maximum self-help by individuals and shall be large enough to permit staff assistance of individuals, if necessary.

17.2.2.8 Bedrooms or other sleeping areas, when provided, shall be separated by gender, and shall have enough space to reasonably provide clean, comfortable accommodations for clients and their belongings.

17.2.3 Furnishings. The agency shall supply furniture for use in all structures used for the provision of licensed/certified services. Furniture shall be comfortable, appropriate for the use intended, well maintained and clean. Nothing in these rules prohibits the use of furniture personally owned by clients in residential programs, provided that the furniture is serviceable, safe, and clean.

17.2.4 Smoking areas. No smoking shall be permitted in any part of the building. To the extent authorized by Maine Law, separate smoking areas shall be provided if smoking is permitted on the grounds. Nothing in these rules requires an agency to permit smoking on its premises.

17.2.5 Nutrition and Food Service. Programs providing prepared meals and snacks shall maintain policies and procedures to govern all aspects of nutrition and food services and shall include but not necessarily be limited to:

17.2.5.1 the planning of menus to meet the nutritional needs of the individuals receiving services, including the provision of special foods, meals, supplements or diets, as applicable.

17.2.5.1.1 Records of menus planned and meals actually served shall be maintained by the program for 90 days and shall be subject to review by the Licensing Authority.

17.2.5.2 purchasing, storage and preparation of food to preserve nutrients and minimize the risk of food borne illness;

17.2.5.3 the consumption of food by staff at the program site;

17.2.5.4 sanitation of the food preparation and service areas, cooking utensils and dishware;

17.2.5.5 Kitchens used to prepare and serve meals for clients being properly equipped and maintained in clean and serviceable condition.

17.2.6 Laundry. Programs providing laundry services for personal clothing or bedding, whether the service is provided by program staff or through a contracted service, or made available to persons receiving services on a self-serve or staff supervised basis, shall maintain policies and procedures to govern all aspects of this service.

17.3 Utilities.

17.3.1 Condition of utilities. Utilities shall be maintained in good repair and in a manner consistent with applicable codes.

17.3.1.1 Electrical systems and fixtures shall be maintained in good repair and shall be adequate for the purpose. Exterior lighting shall be adequate to ensure safety.

17.3.1.2 Heating elements shall be installed, operated, and insulated in a manner that ensures safety. Only approved heat sources shall be used.

17.3.2 Telephone services. Telephone services shall be provided in all structures used for the provision of licensed/certified services. They may be hard-wired or portable/cellular, at the agency's discretion; however, client confidentiality must be assured.

17.3.3 Water. Water derived from sources other than an approved public water supply shall be subjected to water analysis by the Maine Department of Health and Human Services, Division of Health Engineering or other approved laboratory on a bi-annual basis at minimum, but no less than is needed to ensure the safety of the water.

17.3.3.1 The agency shall maintain records of compliance with this rule and shall maintain records of interventions taken to remedy any findings requiring correction, and the results of the interventions.

17.3.3.2 Heated water accessible to individuals in care for personal use shall be regulated so as not to cause burns.

17.4 Grounds.

17.4.1 Hazards. The agency shall maintain the grounds of buildings used in the provision of licensed/certified services in a manner which ensures that they are free from any hazard to health or safety.

17.4.2 Unreasonable Risk. Areas presenting an unreasonable risk to persons receiving residential services such as steep grades, cliffs, open pits, swimming pools, high voltage transformers, or high speed roads, shall be fenced or have erected natural barriers sufficient to prevent access. Fences and natural barriers shall be maintained in good repair.

17.5 Safety and Sanitation.

17.5.1 Garbage. Garbage and rubbish shall be stored securely in noncombustible, covered containers separate from inside living areas or other areas that compromise the safety of persons receiving services, and shall be removed on a regular basis.

17.5.2 Routine Maintenance and Cleaning. There shall be evidence of routine maintenance and cleaning programs in all areas of all agency buildings or structures used for the provision of licensed/certified services.

17.5.2.1 Policies governing the provision of housekeeping services shall be maintained.

17.5.2.2 Policies governing the provision of grounds maintenance services shall be maintained.

17.5.3 Storage areas. The agency shall provide secured storage space in every building or location used for the provision of licensed/certified services for all potentially harmful materials.

17.5.3.1 Outbuildings shall be secured at all times when not in use.

17.5.3.2 Poisonous or toxic materials shall be labeled and stored in locked storage spaces that are not used for any other purpose.

17.5.3.3 Poisonous, toxic, or flammable materials and their containers shall be stored, used and disposed of in compliance with all applicable regulations, rules and laws.

17.5.4 Power Driven Equipment. Power driven equipment shall be maintained in safe and good repair. Safety features shall not be disabled, disconnected or removed and shall be in use during operation. Use of power driven equipment by clients, when appropriate, shall be monitored by staff.

17.5.5 Firearms. Firearms, ammunition and other weapons shall not be permitted on the grounds or within the building of any structure under agency control used for the delivery of licensed/certified services, except as required for law enforcement officers.

17.5.6 Swimming Pools. Swimming pools shall be maintained free from contamination in accordance with Department of Health and Human Services, Division of Health Engineering standards. When individuals receiving care have access to the pool, the agency shall have on duty an individual who has a current water safety instructor certificate or senior lifesaving certificate from the Red Cross or its equivalent.

17.5.7 Domestic Animals. The agency shall ensure that domestic animals kept or maintained at any building or location under control of the agency shall have current and appropriate vaccinations as required by law and shall otherwise be maintained according to applicable law, rule and regulation.

17.5.8 Transportation. The agency shall ensure that there are policies governing the transportation of clients.

17.5.8.1 all vehicles used to transport clients shall be in a safe condition, and equipped in a manner consistent with the seasons.

17.5.8.2 the number of people permitted in any vehicle shall not exceed the number of seats and seat belts available and in working condition.

17.5.8.3 there shall be staff supervision in any vehicle used to transport clients adequate to manage the situation.

17.5.9 Routine and Emergency Health Care. There shall be specific policies and procedures governing the provision of routine and emergency health care to persons receiving services. The policies and procedures shall be specific to the needs of the population served, services provided, and duration of service delivery. The policies and procedures shall describe the extent of services provided, may include a statement that specific services are not provided or arranged by the program, or may describe the method to summon emergency help from other resources. The policies and procedures shall address, but not necessarily be limited to:

17.5.9.1 emergency medical services, including intervention in suicides, which shall be available during all the times the program is operational,

17.5.9.2 emergency psychiatric services,

17.5.9.3 emergency transportation, which shall be accessible during all the times the program is operational,

17.5.9.4 first aid and CPR administration by trained program staff, including the maintenance of first aid supplies adequate to meet situations reasonably anticipated.

17.5.10 Management of infectious diseases. The agency shall have written policies and procedures governing the management of infectious diseases, to include at minimum screening policies and procedures and maintenance of universal precautions.

17.5.10.1 The infectious diseases include, but are not necessarily limited to, HIV (Human Immunodeficiency Virus), tuberculosis, Hepatitis (any type), rubella (measles), mumps, varicella (chicken pox), pediculosis (lice), scabies (e.g., *Sarcoptes scabiei*).

17.5.10.2 Screening policies applicable to both clients and staff shall address the criteria for testing and referrals to further treatment, and must consider the limits of inquiry allowed by law (i.e., HIV screening).

17.5.10.3 Universal precautions and other precautions recommended by the Maine Center for Disease Control and Prevention, the US Public Health Service or the Centers for Disease Control, as applicable, shall be enforced.

17.5.11 Sewage. Sewage disposal systems other than public systems shall be maintained in proper working order to prevent back flow, over flow, seepage, or other circumstances capable of risking the health of persons using the building.

17.6 Emergency Management Plans. The agency shall adopt written procedures for staff and clients to follow in case of emergency or disaster.

17.6.1 Plan Development. Plans shall be developed with the assistance of qualified fire, health and safety personnel and shall include, but not necessarily be limited to:

17.6.1.1 evacuation of all buildings;

17.6.1.2 assignment and deployment of staff during emergencies;

17.6.1.3 notification of guardians, the placement agency and the Licensing Authority, as applicable;

17.6.1.4 management of medical and psychiatric emergencies;

17.6.1.5 searches for lost persons, if applicable; and

17.6.1.6 weather emergencies.

17.6.2 Staff Access to Plans. Copies of emergency management plans shall be readily available to all staff at all times.

17.6.3 Emergency Practices. Emergency practices shall be developed and implemented, and shall include but not necessarily be limited to:

17.6.3.1 posting emergency numbers adjacent to telephones for fire, police, physician(s), poison control, health agency and ambulance;

17.6.3.2 posting fire evacuation procedures in conspicuous locations throughout buildings;

17.6.3.3 instructing clients and staff in fire prevention, reporting, management and building evacuation;

17.6.3.4 training all staff on all shifts to perform assigned tasks during emergencies, including the use and location of fire fighting equipment. The occupants of each agency building utilized in the provision of licensed/certified services shall be drilled in emergency procedures, including actual evacuation of individuals to safe areas four (4) times per year for non-residential programs and monthly for residential programs, unless a higher standard is required by the State Fire Marshall.

17.6.3.4.1 Emergency drills shall be held at unexpected times and under varying conditions to simulate the possible conditions of fires or other disasters.

17.6.3.4.2 Records of such emergency drills shall be maintained, noting dates and time, evacuation time, exits used, problems or barriers encountered and the corrective measures to be implemented henceforth.

17.6.3.5 developing and implementing plans for the evacuation of any individuals, who may be physically, emotionally or perceptually impaired, and who are likely to be served by the agency.

17.7 Medication administration. There shall be specific policies and procedures governing the acquisition, storage, administration and disposal of prescription and over-the-counter medication, consistent with the services provided at the program.

17.7.1 The policies and procedures shall include, but not necessarily be limited to:

17.7.1.1 identification of staff positions authorized and appropriately credentialed to order, dispense, acquire, store, administer or dispose of medication, including schedule drugs and psychotropic medication;

17.7.1.2 specific training and supervision required of staff so authorized;

17.7.1.3 procedures to order, dispense, acquire, store, administer or dispose of medication, including scheduled drugs and psychotropic medication;

17.7.1.4 procedures for the acquisition of informed consent from the person for whom the medication is ordered, and the guardian if one has been appointed, including cases of emergency. This shall include the following:

17.7.1.4.1 The acquisition of informed consent and signatures of persons aged 14 and older obtained prior to the first administration of any psychotropic medication and again prior to the first administration of any change in medication, dosage or route of administration, unless documentation of clinical incapacity exists in the client record.

17.7.1.4.2 The exercise of the client and guardian's rights to revoke consent, in writing or verbally, at any time, and the resulting actions to be taken by the agency, including consultation with the prescribing physician.

17.7.1.5 the identification and documentation of drug or medication allergies or significant side effects;

17.7.1.6 documentation of administration or refusal of medication, including dosage, route and timing;

17.7.1.7 medication errors, accidental or intentional overdoses, allergic reactions or significant side effects. This must include the agency's review of related critical incidents and development and implementation of plans for improvement based on the review and the method to ensure notification to the Office of Substance Abuse within 24 hours of the incident;

17.7.1.8 the acquisition, identification, storage, administration and disposal of medication;

17.7.1.9 the provision for daily monitoring and documentation of the condition of each client who receives medication administered by the program, to specifically address the presence or absence of expected outcomes, behavioral changes, or side effects.

18.0 CLIENT RIGHTS AND ACCESS TO TREATMENT

18.1 Information about Rights.

18.1.1 Client Notification. Clients will be fully informed at the time of admission and as needed during ongoing treatment, of their rights and responsibilities, and of all the rules and regulations governing client conduct and responsibilities. Documentation of this will be found in each client record. Such rights and responsibilities shall be posted at the treatment site and provided to the client in writing or in other format sufficient to ensure that the client can understand. Clients who are unable to read English shall have the rules and regulations explained verbally or translated. The provision of copies of the rights and responsibilities or the explanation/translation shall be documented in writing, and placed in the client's record.

18.1.2 Ongoing assistance. Clients will be encouraged and assisted throughout treatment to understand and exercise their rights as clients, including rights:

18.1.2.1 To report, without fear of retribution, any instances of suspected abuse, neglect, or exploitation of clients being served in the program;

18.1.2.2 To use a grievance and appeal process, in accordance with State laws and regulations;

18.1.2.3 To provide Input into program policies and services through client satisfaction surveys;

18.1.2.4 To choose and designate a personal advocate, who can speak for or on the behalf of the client, and who is protected from fears of retaliation, retribution or coercion in the exercise of advocacy.

18.1.3 Program rules and client non-compliance. Clients have the right to be informed of program rules and the consequences of non-compliance. Program rules shall be confined to those that ensure good order and the safety and health of clients and staff, shall not be overly restrictive in their scope or consequence, and shall not be applied arbitrarily or capriciously. Involuntary withdrawal of medication or discharge from treatment shall be a sanction of last resort.

18.2 Treatment Rights.

18.2.1 Right to choice of provider. Clients have the right to a choice of health care providers that is sufficient to ensure access to appropriate high-quality health care. They have the right to change providers without fear of coercion, retaliation, the imposition of administrative sanctions, or requirements imposed that have no reasonable role in the orderly and timely transfer of care.

18.2.2 Non-discrimination. Treatment provided will be fair and impartial regardless of age, race, sex, color, physical or mental impairment, religion or ancestry, familial or marital status, sexual orientation, genetic information, or source of payment. Treatment will be provided in an atmosphere of dignity and trust between program, program staff and client.

18.2.3 Treatment standards. Treatment will be provided according to accepted clinical practice, taking into account the individual needs of the client, and shall be adequate and humane.

18.2.4 Least restrictive treatment. Clients will receive services within the least restrictive and most accommodating environment possible. Consideration shall be made of individual needs, including work and family responsibilities, to provide treatment and access to services that is most accommodating, and least intrusive and disruptive for most clients. Restrictions on access to services shall be limited to those that constitute legitimate operational requirements and the maintenance of good order.

18.2.5 Client involvement in treatment choices. Changes in treatment regimens, including changes in time schedules, dosing schedules or amounts, or any other element of a treatment plan, shall be made with the full involvement and consent of the client. Changes shall not be arbitrary, capricious, done solely for the convenience of the provider, or without clinical merit.

18.3 Right to Give and Withhold Consent.

18.3.1 Clients have the right to the option to give or withhold informed consent prior to being involved in research projects, and the right to retain a copy of the informed consent form.

18.4 Rights to Confidentiality.

18.4.1 Protection of confidentiality. Clients have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected.

18.4.2 Access to records. Clients also have the right to review and have a copy of their own medical records and request amendments to their records.

18.4.3 Information about limits of confidentiality. Clients have the right to be informed of the extent and limits of confidentiality, including the conditions under which information can be released without client consent, the use of identifying information for purposes of central registry, program evaluation, billing, and statutory requirements for reporting abuse.

18.5 Complaints and Grievances.

18.5.1 All clients have the right to a fair and efficient process for resolving differences with health care providers. Programs shall develop and display or otherwise make available to clients grievance procedures that specify the process for dispute resolution. The following elements must be assured:

18.5.1.1 clients may express verbally or in writing their dissatisfaction or complaints;

18.5.1.2 clients may initiate grievance procedures and pursue those procedures;

18.5.1.3 the review of the complaint or grievance by a party other than staff member(s) involved in the dispute;

18.5.1.4 the receipt of a decision in writing, with the reasoning articulated; and

18.5.1.5 time frames and deadlines that are reasonable and fair, and that apply to both the client and the provider. Minimally, responses should occur within ten working days at each step of the process, unless time extensions are agreed upon by all parties. The time frame will apply to both client and the provider and must be included in the written explanation of rights.

18.6 Policies and Procedures Regarding Client Rights.

18.6.1 Policies regarding rights and exceptions. There shall be written policies and procedures designed to enhance the dignity of all clients and to protect their civil rights.

18.6.1.1 Residential facilities shall develop policies around visitation, telephone privileges, and client mail.

18.6.1.2 Any program making exceptions to or restrictions of the rights of a client, shall record the exception in the client's record. The exception must be signed by the administrator or physician.

18.6.2 Written explanation of rights. A handout explaining client's rights, fee schedule, program rules and regulations shall be prepared.

18.6.2.1 The handout shall be provided to each client on admission.

18.6.2.2 A copy of the handout shall be posted in a prominent place accessible to all clients.

18.6.2.3 A document of receipt of these forms shall be maintained in the client record.

18.6.3 Client fees.

18.6.3.1 A reasonable fee shall be assessed for service.

18.6.3.2 A client who has the means to pay shall not be exempted from reasonable fees.

18.6.3.3 Client eligibility for government or private sector benefits shall be assessed and whenever possible, enrollment sought. If it is determined that clients are eligible for government or private sector benefits, they will be encouraged to apply.

18.6.4 Human Subject Research.

18.6.4.1 No client shall be allowed to participate in any experimental or research project without the full knowledge, understanding and written consent of the client (and legal guardian if appropriate).

18.6.4.2 All experimental or research projects conducted shall comply with applicable state and federal laws, rules, regulations, and guidelines.

18.7 Policies and Procedures Regarding Access to Treatment.

18.7.1 Adaptive Equipment. There shall be specific policies and procedures governing the availability and provision of adaptive equipment and auxiliary aids.

18.7.2 Interpretive Services. There shall be specific policies and procedures governing the availability and provision of interpretive services, whether spoken language or sign.

19.0 SUBSTANCE ABUSE TREATMENT SERVICES

19.1 Medically Managed Intensive Inpatient Detoxification (ASAM Level IV-D).

19.1.1 Definition. Medically managed intensive inpatient detoxification programs provide services to persons who are experiencing severe withdrawal symptoms and therefore require full medical acute care services in a twenty-four hour hospital setting. Services include a biopsychosocial evaluation, medical observation, monitoring, and treatment, counseling, and follow-up referral. Services shall be delivered in an appropriately licensed/certified acute care inpatient setting, adhering to medically-approved procedures and protocols.

19.1.2 Services provided. Medically managed intensive inpatient detoxification programs will provide immediate medical evaluation and continued medical management, including:

19.1.2.1 Highly individualized biomedical, emotional, behavioral, and addiction treatment. This includes the management of all concomitant biomedical, emotional, behavioral, and cognitive conditions in the context of addiction treatment;

19.1.2.2 Availability of hourly or more frequent nurse monitoring;

19.1.2.3 A range of cognitive, behavioral, medical, mental health, and other therapies, to enhance the client's understanding of addiction, the completion of the detoxification process, and referral for continuing treatment and support;

19.1.2.4 Health education services;

19.1.2.5 Services to families and significant others;

19.1.2.6 Availability of specialized medical consultation. Providers of detoxification services shall make and maintain arrangements with external clinicians and facilities for referral of the client for specialized services beyond the capability of the program;

19.1.2.7 Full medical acute care services;

19.1.2.8 Intensive care, as needed;

19.1.2.9 Nutritional services, including special diets, as needed.

19.1.3 Staff.

19.1.3.1 Medically managed intensive inpatient detoxification programs shall be staffed by physicians or physician extenders who are available 24 hours a day as an active member of an interdisciplinary team of appropriately trained professionals, and who medically manage the care of the client.

19.1.3.2 A registered nurse or other licensed and credentialed nurse shall be available for primary nursing care and observation 24 hours a day.

19.1.3.3 An alcohol and drug counselor shall be available 8 hours a day to administer planned interventions according to the assessed needs of the client.

19.1.3.4 An interdisciplinary team of appropriately trained clinicians shall be available to assess and treat the client with a substance-related disorder, or an addicted client with a concomitant acute biomedical, emotional, or behavioral disorder.

19.1.4 Client records.

19.1.4.1 Elements of the assessment and treatment plan will include, but not be limited to:

19.1.4.1.1 A comprehensive nursing assessment, performed at admission;

19.1.4.1.2 Approval of the admission by a physician;

19.1.4.1.3 A record of a comprehensive history and physical examination performed within 24 hours of admission, accompanied by appropriate laboratory and toxicology tests OR the evaluation of the records of a physical examination administered within the preceding 7 calendar days prior to admission, by a physician or physician extender;

19.1.4.1.4 An addiction-focused history, obtained as part of the initial assessment and reviewed by a physician during the admission process;

19.1.4.1.5 Sufficient biopsychosocial screening assessments to determine placement, and for the individualized care plan to address treatment priorities. This assessment must be completed as soon as the client is medically stable, but no later than the fourth day of admission, to include screening for history of abuse or trauma;

19.1.4.1.6 An individualized treatment plan, including problem identification, treatment goals, measurable treatment objectives, and activities designed to meet those objectives.

19.1.4.2 Other documentation will include:

19.1.4.2.1 Progress notes entered by clinical staff at least once in each 24 hour period that clearly reflect implementation of the treatment plan and the client's response to treatment, as well as subsequent amendments to the plan;

19.1.4.2.2 Detoxification rating scale tables and flow sheets, as needed;

19.1.4.2.3 Physician services, documented in the client record as they occur;

19.1.4.2.4 Notes of client progress entered by nurses at least once each shift or every 8 hours;

19.1.4.2.5 A record of discharge/transfer planning, beginning at admission.

19.1.5 Methadone detoxification. Persons presenting symptoms of severe opiate withdrawal in a residential setting may require the use of methadone to facilitate a successful withdrawal. The administration of methadone to facilitate detoxification will require compliance with a variety of Federal and State of Maine laws, and will also involve oversight by Federal and State agencies to monitor compliance with these laws. The detoxification process using methadone involves the reduction of dosage from the stabilization dosage to a zero dosage upon discharge. Methadone detoxification programs must meet the following requirements:

19.1.5.1 Programs using methadone must include documentation of approval from and compliance with regulations of the Substance

Abuse and Mental Health Services Administration (SAMHSA), the Federal Drug Enforcement Administration, the Maine State Pharmacy Board, and the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services, Medical Facilities Unit.

19.1.5.2 Also required is proof of appropriate accreditation by the Joint Commission for the Accreditation of Health Care Organizations, or the Commission on Accreditation of Rehabilitation Facilities. Detoxification programs that employ the services of a physician certified by the American Society of Addiction Medicine must provide a copy of such certificate.

19.1.5.3 Programs using methadone must submit de-identified client data to the Office of Substance Abuse on forms provided by the office. This data will be made available only for research and program evaluation functions.

19.2 Freestanding Residential Detoxification (ASAM Level III 7-D).

19.2.1 Definition. Freestanding residential detoxification programs provide care to persons whose withdrawal signs and symptoms indicate the need for 24-hour residential care. Services include a biopsychosocial evaluation, medical observation, monitoring, and treatment, counseling, and follow-up referral. However, the full resources of an acute care general hospital or a medically managed intensive inpatient treatment program are not necessary. Services must be conducted in a freestanding or other appropriately licensed/certified healthcare or addiction treatment facility.

19.2.2 Services provided. The freestanding residential detoxification program will provide immediate medical evaluation and continued medical management, including:

19.2.2.1 group therapies, and withdrawal support;

19.2.2.2 Availability of hourly or more frequent nurse monitoring;

19.2.2.3 A range of cognitive, behavioral, medical, mental health, and other therapies, designed to enhance the client's understanding of addiction, the completion of the detoxification process, and referral for continuing treatment and support;

19.2.2.4 Health education services;

19.2.2.5 Services to families and significant others;

19.2.2.6 Availability of specialized clinical consultation and supervision for biomedical, emotional, and behavioral and cognitive problems. Providers of detoxification services shall make and maintain arrangements with external clinicians and facilities for referral of the member for specialized services beyond the capability of the program;

19.2.2.7 Direct affiliation with other levels of care;

19.2.2.8 Ability to conduct or arrange for appropriate laboratory and toxicology tests;

19.2.2.9 Nutritional services, including special diets, as needed.

19.2.3 Staff.

19.2.3.1 Freestanding residential detoxification programs shall be staffed by physicians or physician extenders who are available 24 hours a day by telephone.

19.2.3.2 A registered nurse or other licensed and credentialed nurse shall be available to conduct a nursing assessment on admission.

19.2.3.3 A nurse shall be on site at all times, and shall be responsible for overseeing the monitoring of the client's progress and medication administration on an hourly basis, as needed.

19.2.3.4 Appropriately licensed and credentialed staff shall be available to administer medications in accordance with physician orders. The level of nursing care must be appropriate to the severity of client need.

19.2.3.5 Appropriately credentialed alcohol and drug counselors shall provide evaluation and treatment services for clients, and family support as needed.

19.2.3.6 An interdisciplinary team of appropriately trained clinicians shall be available to assess and treat the client and to obtain and interpret information regarding the client's needs. The number and disciplines of team members are appropriate to the range and severity of the client's problems.

19.2.4 Client records.

19.2.4.1 Elements of the assessment and treatment plan will include, but not be limited to:

19.2.4.1.1 An addiction-focused history, obtained as part of the initial assessment and reviewed by a physician during the admission process;

19.2.4.1.2 A record of a physical examination by a physician or physician extender, performed within 48 hours of admission, accompanied by appropriate laboratory and toxicology tests OR the evaluation of the records of a physical examination administered within the preceding 7 calendar days prior to admission, by a physician or physician extender;

19.2.4.1.3 Sufficient biopsychosocial screening assessments to determine the level of care in which the client should be placed and for the individualized care plan to address treatment priorities;

19.2.4.1.4 An individualized treatment plan, including problem identification, treatment goals, measurable treatment objectives, and activities designed to meet those objectives.

19.2.4.2 Other documentation will include:

19.2.4.2.1 Progress notes that clearly reflect implementation of the treatment plan and the client's response to treatment, as well as subsequent amendments to the plan;

19.2.4.2.2 Detoxification rating scale tables and flow sheets, as needed;

19.2.4.2.3 Physician services, documented in the client record as they occur;

19.2.4.2.4 Notes of client progress entered by nurses at least once each shift or every 8 hours;

19.2.4.2.5 Notes of client progress entered by clinical staff at least once in each 24 hour period;

19.2.4.2.6 A record of discharge/transfer planning, beginning at admission.

19.2.5 Methadone detoxification. Persons presenting symptoms of severe opiate withdrawal in a residential setting may require the use of methadone to facilitate a successful withdrawal. The administration of methadone to facilitate detoxification will require compliance with a variety of Federal and State of Maine laws, and will also involve oversight by Federal and State agencies to monitor compliance with these laws. The detoxification process using methadone involves the reduction of dosage from the stabilization dosage to a zero dosage upon discharge. Methadone detoxification programs must meet the following requirements:

19.2.5.1 Programs using methadone must include documentation of approval from and compliance with regulations of the United States Food and Drug Administration, the Federal Drug Enforcement Administration, the Maine State Pharmacy Board, and the Maine Department of Health and Human Services, Division of Licensing and Regulatory Services, Medical Facilities Unit.

19.2.5.2 Also required is proof of appropriate accreditation by the Joint Commission for the Accreditation of Health Care Organizations, or the Commission on Accreditation of Rehabilitation Facilities. Detoxification programs who employ the services of a physician certified by the American Society of Addiction Medicine must provide a copy of such certificate.

19.3 Outpatient Detoxification (ASAM Level I-D and Level II-D).

19.3.1 Definition. Outpatient detoxification programs provide services to persons who are experiencing no more than moderate withdrawal symptoms, and do not have co-morbid medical or psychiatric conditions that require 24-hour inpatient care. Services include a biopsychosocial evaluation, medical observation, monitoring, and follow-up referral. Services may be conducted in a freestanding or other appropriately licensed healthcare or addiction treatment facility. Clients experiencing, or at risk of experiencing acute withdrawal syndrome are not appropriate candidates for outpatient detoxification.

19.3.2 Services provided. The outpatient detoxification program shall provide immediate medical evaluation and continued medical management in an ambulatory setting, including:

19.3.2.1 daily medical monitoring and management of acute withdrawal symptoms;

19.3.2.2 biopsychosocial assessment, including assessment of availability of support for the client in the community;

19.3.2.3 appropriate referrals for further mental health or medical consultation;

19.3.2.4 24-hour access to medical care;

19.3.2.5 assessment of clients' medical and behavioral symptoms on at least a daily basis;

19.3.2.6 planning for and referral to further treatment.

19.3.3 Staff.

19.3.3.1 Outpatient detoxification programs will be staffed by physicians or physician extenders who are available 24 hours a day by telephone.

193.3.2 A registered nurse or other licensed and credentialed nurse shall be available to conduct a nursing assessment on admission.

19.3.3.3 An interdisciplinary team of appropriately trained clinicians shall be available to assess and treat the client with a substance-related disorder, or an addicted client with a co-occurring acute biomedical, emotional, or behavioral disorder.

19.3.4 Client records.

19.3.4.1 Elements of the assessment and treatment plan will include, but not be limited to:

19.3.4.1.1 An addiction-focused history, obtained as part of the initial assessment and reviewed by a physician during the admission process;

19.3.4.1.2 A record of a physical examination by a physician or physician extender, performed within 24 hours of admission, accompanied by appropriate laboratory and toxicology tests OR the evaluation of the records of a physical examination administered

within the preceding 7 calendar days prior to admission, by a physician or physician extender;

19.3.4.1.3 Sufficient biopsychosocial screening assessments to determine the level of care in which the client should be placed and for the individualized care plan to address treatment priorities;

19.3.4.1.4 An individualized treatment plan, including problem identification, treatment goals, measurable treatment objectives, and activities designed to meet those objectives.

19.3.4.2 Other documentation will include:

19.3.4.2.1 Progress notes that clearly reflect implementation of the treatment plan and the client's response to treatment, as well as subsequent amendments to the plan;

19.3.4.2.2 Detoxification rating scale tables and flow sheets, as needed;

19.3.4.2.3 Physician services, documented in the client record as they occur;

19.3.4.2.4 Notes of client progress entered by nurses at least once daily;

19.3.4.2.5 Notes of client progress entered by clinical staff at least once daily;

19.3.4.2.6 A record of discharge/transfer planning, beginning at admission.

19.4 Shelter Services.

19.4.1 Definition. Shelter is a service which provides food, lodging and clothing for abusers of alcohol and other drugs, with the purpose of protecting and maintaining life and providing motivation for alcohol and drug treatment.

19.4.2 Services Provided. Services provided will include but not necessarily be limited to:

19.4.2.1 food and beverages when the shelter is in operation;

19.4.2.2 clean clothing, with laundry facilities available on the premises;

19.4.2.3 clean bedding;

19.4.2.4 shower or bathing facilities;

19.4.2.5 supplies for personal hygiene;

19.4.2.6 referral to detoxification or other suitable treatment, as needed;

19.4.2.7 arrangements for needed health care services through written agreements with detoxification centers, hospitals, and other emergency care facilities;

19.4.2.8 encouragement for participation in self-help groups;

19.4.2.9 transportation between the program and emergency healthcare facilities.

19.4.3 Staff. In addition to the General Requirements listed above, staff will receive training:

19.4.3.1 to carry out emergency procedures, including CPR and first aid, and become certified in these procedures;

19.4.3.2 to recognize signs that could indicate the physical deterioration of a client;

19.4.3.3 to recognize suicidal indicators and to notify clinical staff if indicators are present;

19.4.3.4 to motivate the client to accept detoxification or other suitable treatment;

19.4.3.5 in referral procedures;

19.4.3.6 to maintain records of shelter utilization;

19.4.3.7 to identify potentially harmful items and to supervise their use.

19.5 Residential Treatment (ASAM Level III).

19.5.1 Definition. Residential treatment programs provide services in a full (24 hours) residential setting. The program shall provide a scheduled treatment regimen which consists of diagnostic, educational, and counseling services; and shall refer clients to support services as needed. Clients are routinely discharged to various levels of follow-up services. There are three categories of residential care:

19.5.2 **Category I** Category I residential treatment programs maintain a basic focus on early recovery skills, including the negative impact of chemical dependency, tools for developing support, and relapse prevention skills. Examples of Category I programs are extended shelters and residential rehabilitation programs. Category I programs are characterized by the following criteria:

19.5.2.1 The term of residency shall not exceed 45 days without documented assessment of client's need for the extension and a treatment plan indicating goals congruent with the definition and purpose of this component.

19.5.2.2 Individual and group counseling at a minimum of 14 hours per week or 2 hours per day for each client. The qualified staff shall teach attitudes, skills and habits conducive to good health and the maintenance of a substance free life style. The treatment mode may vary with the member's needs and may be in the form of individual, group or family counseling at a minimum of fourteen (14) hours per week.

19.5.2.3 daily didactic/educational presentations.

19.5.2.4 Programs shall have staff coverage 24 hours a day, including weekend coverage. The program shall maintain a medical staffing pattern that enables it to meet the physical care requirements delineated above. Physician back-up and on-call staff shall be provided to deal with medical emergencies. The program shall not subcontract any of its obligations and rights pertaining to medical services described in this section. For the purposes of this section, physician consultant services are not considered subcontracting.

19.5.3 **Category II** Category II programs provide a structured residential milieu, to help clients transition from a substance abusing lifestyle to a

solid recovery environment. Clients may initially receive a treatment focus similar to that of Category I programs, but will transition to a treatment focus that addresses the cultural, social, educational, and vocational needs of the client. An example of a Category II program is a halfway house. Category II programs are characterized by the following criteria:

19.5.3.1 length of treatment: up to 180 days duration

19.5.3.2 group/individual/family treatment sessions appropriate to the phase of treatment

19.5.3.3 living skills training according to the phase of treatment

19.5.3.4 vocational assessment and preparation

19.5.3.5 supervised housekeeping responsibilities

19.5.4 **Category III** Category III programs provide a long-term supportive and structured environment for chemically dependent clients with extensive substance abuse debilitation. These programs provide a supervised living experience within the program. Qualified staff shall teach attitudes, skills and habits conducive to facilitating the member's transition back to the community. The treatment mode may vary with the member's needs and may be in the form of individual, group or family counseling. Outcome goals may range from custodial care to further treatment services and recovery. Examples of Category III programs are adolescent long-term rehabilitation or an extended care program. Category III programs are characterized by the following criteria:

19.5.4.1 length of treatment: over 180 days duration

19.5.4.2 group/individual/family treatment sessions appropriate to the phase of treatment

19.5.4.3 living skills training according to the phase of treatment

19.5.4.4 vocational assessment and preparation

19.5.4.5 supervised housekeeping responsibilities

19.5.4.6 transportation shall be available 24 hours a day. A written agreement shall provide for transportation between the program and emergency care facilities.

19.5.4.7 The program shall have a written agreement with an ambulance service to assure twenty-four (24) hour access to transportation to emergency medical care facilities for members requiring such transport. Physician back-up and on-call staff shall be provided to deal with medical emergencies.

19.5.4.8 A program shall not subcontract any of its obligations and rights pertaining to medical services described in these regulations with the exception of physician consultant services.

19.5.4.9 Extended care services shall provide a scheduled therapeutic plan consisting of treatment services designed to enable the member to sustain a substance free life style within a supportive environment.

19.5.5 Services provided. The services shall depend upon the treatment needs of the individual clients. Services provided either on site or through referral shall include but not be limited to:

19.5.5.1 Evaluation of the client's medical and psycho-social needs;

19.5.5.2 A medical examination by the program's physician within 5 days of admission unless the physician has approved a prior examination conducted within the last 30 days;

19.5.5.3 Opportunities for learning basic living skills, such as personal hygiene skills, knowledge of proper diet and meal preparation, constructive use of leisure time, money management, and interpersonal relationship skills;

19.5.5.4 Clinical services, including individual and group counseling;

19.5.5.5 Provisions for family involvement;

19.5.5.6 Educational services, vocational placement and training, and recreational opportunities as appropriate to the client group to be served;

19.5.5.7 Encouragement for participation in self-help groups.

The program shall make agreements with community resources to provide client services through referrals when the program is unable to provide them.

19.6 Intensive Outpatient Program (IOP) (ASAM Level II.1).

19.6.1 Definition. Intensive Outpatient Programs provide an intensive and structured program of alcohol and other drug assessment and group treatment services in a setting which does not include an overnight stay. These programs include a structured sequence of multi-hour clinical and educational sessions scheduled for a minimum of six (6) and maximum of twenty (20) hours per week per client. Any exceptions to these time frames must be approved in advance by OSA.

19.6.2 Services Provided.

19.6.2.1 procedures to determine the client's medical needs. The program will determine the necessity for medical examination and further consultation. The medical assessment will be part of the case record;

19.6.2.2 biopsychosocial assessment, as outlined in Section 15.6;

19.6.2.3 clinical services, to include daily didactic and counseling groups;

19.6.2.4 educational chemical dependency groups;

19.6.2.5 involvement of affected others;

19.6.2.6 planning for and referral to further treatment, as needed.

19.7 Outpatient Care (ASAM Level I).

19.7.1 Definition. Outpatient Care provides assessment and counseling services to chemically dependent clients and affected others.

19.7.2 Services provided.

19.7.2.1 services offered according to client need on a scheduled or emergency basis;

19.7.2.2 individual, group, and family counseling;

19.7.2.3 procedures to determine the client's medical needs. The program will determine the necessity for medical examination and further consultation. The medical assessment will be part of the case record;

19.7.2.4 biopsychosocial assessment, as outlined in Section 15.6. The program will make appropriate referrals for further mental health consultation;

19.7.2.5 services to the client, through referral, in the area of educational enrichment, vocational placement and training, legal services, and money management, as dictated by client needs;

19.7.2.6 planning for and referral to further treatment;

19.7.2.7 education about chemical abuse.

19.8 Opioid Supervised Withdrawal And Maintenance Treatment Module.

19.8.1 Scope of Regulations. Opioid supervised withdrawal and maintenance are adjunctive treatments for individuals with a current serious physiological opiate addiction. A client must have an addiction of at least one year duration in order to qualify for maintenance treatment. The administration of opioid agonists will require compliance with a variety of Federal and Maine State laws, and will also involve oversight by Federal and State agencies to monitor compliance with these laws and regulations. Opioid maintenance and treatment involves the administration of specific opioid agonists under the supervision of the program Medical Director.

19.8.2 General Requirements. Opioid Treatment Programs (OTPs) shall meet the following requirements, in addition to the requirements of Sections 2.0 through 19.0 of these rules:

19.8.2.1 OTPs shall be open seven days weekly, including all holidays;

19.8.2.2 OTPs shall limit their program size to no more than 500 clients at each licensed/certified site. Waivers may be granted by OSA for specific program sites to exceed this limit if the program can demonstrate:

19.8.2.2.1 The physical plant is adequate to accommodate the proposed number of clients;

19.8.2.2.2 The ability to hire and retain adequate numbers of qualified staff to meet the standards in this rule;

19.8.2.2.3 A demonstrated need for increased services that cannot be reasonably met except by expansion of the program size; and

19.8.2.2.4 Written agreement by the program to accept the conditions of the waiver as enforceable as rule.

19.8.2.3 OTPs shall demonstrate compliance with:

19.8.2.3.1 42 CFR Chapter 1, Subchapter A, Part 8, as amended, including but not limited to, possession of a current, valid certificate from the Substance Abuse and Mental Health Services Administration within the U.S. Department of Health and Human Services (SAMHSA), which shall be the demonstration of compliance with Sections 303(g)(1) of the Controlled Substances Act (21 United States Code (USC) Section 823(g)(1)), as amended, to dispense opioid drugs in the treatment of opioid addiction. This will depend upon the OTP obtaining accreditation from an accreditation body that has been approved by SAMHSA; and

19.8.2.3.2 Chapter 45 of the Maine Criminal Code (17-A M.R.S.A. § 1101 et seq.), as amended, and the Maine State Pharmacy Act (32 M.R.S.A § 13731(2)), as amended, and Sections 2.0-19.0 of these rules. Compliance shall be subject to the review and independent verification of the Licensing Authority.

19.8.2.4 Prior to admitting a client, OTPs shall submit client data to the Office of Substance Abuse (OSA) according to

specifications as shall be determined by OSA. The specifications shall include content, form, format, frequency, and due date for submission. This data will be made available only for research and program evaluation functions.

19.8.2.5 Prior to admission to an OTP, the OTP shall confirm using OSA's data collection system that the client is not currently enrolled in another OTP. In the event that the data collection system is inoperable or unavailable, the OTP shall check with all other OTPs within three calendar days of admission to the OTP.

19.8.2.5.1 The OTP shall obtain from the client all releases of information necessary to conduct this confirmation.

19.8.2.5.2 Documentation that such a confirmation has been made shall be noted in the client record.

19.8.2.6 As part of the quality assurance plan required by 42 CFR §8.12(c)(2), OTPs shall maintain a current Diversion Control Plan that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use, and that assigns specific responsibility to the medical director and the program manager for carrying out the diversion control measures and functions described in the Diversion Control Plan.

19.8.2.7 There shall be a current plan for emergency administration of medications in case the program is required to close temporarily on an emergency basis, including how clients are to be informed of these emergency arrangements.

19.8.2.8 There shall be a current disaster plan, that shall address at least the following:

19.8.2.8.1 Natural disasters and man-made disasters, or other serious events;

19.8.2.8.2 Disasters that may occur when the OTP is open and when it is closed;

19.8.2.8.3 Security of medication and records;

19.8.2.8.4 Safety of clients and staff, including an evacuation plan; and

19.8.2.8.5 Any other situation that is unique to the OTP.

19.8.2.9 There shall be current procedures to ensure that the informed written consent to treatment of clients is received. Specifically, the OTP shall:

19.8.2.9.1 Ensure that admission is voluntary;

19.8.2.9.2 Ensure that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the client. This will include, but not necessarily be limited to, the risks and benefits of treatment, other treatment options, and the fact that opioid agonist drugs cause dependence and dosage tolerance;

19.8.2.9.3 Ensure that the reasons for and ramifications of administrative supervised withdrawal are explained to the client; and

19.8.2.9.4 Acquire and maintain documentation that shall include the Client Rights and Responsibility Disclosure Forms signed by the client, and USFDA Form 2635 "Consent to Treatment with an Approved Narcotic Drug."

19.8.2.10 OTPs shall develop and follow policies and procedures to effect orderly transfers of clients between substance abuse programs. Records shall be provided promptly to the receiving substance abuse program. Records shall be complete at the time of transfer. Reports to OSA data collection system shall be completed at the time of transfer.

19.8.2.11 OTPs shall develop and follow policies and procedures, consistent with best practices and applicable law and rule, governing administrative withdrawal. Administrative

withdrawal may not be used by OTPs to discipline clients for minor infractions of program policy. Clients who are involuntarily withdrawn from treatment for administrative reasons shall be treated with compassion, respect and dignity. Dosage withdrawal schedules shall be developed and documented for each individual client being administratively withdrawn, considering the maintenance dosage, individual tolerance of dosage reduction, and psychiatric and medical comorbidities.

19.8.2.12 OTPs shall adhere to critical incident reporting procedures required by OSA.

19.8.2.13 OTPs shall invite municipal officials including but not limited to elected officials, public health and public safety officials to an annual meeting with clinic management and Office of Substance Abuse staff to discuss the clinic's impact on the municipality.

19.8.3 Required Services. OTPs shall provide adequate medical, counseling, vocational, educational and other assessment and treatment services that are fully and reasonably available to clients.

19.8.3.1 The services may be provided by the OTP at the OTP primary site or through an affiliated agreement. All assessments, evaluations and interventions shall be documented in the client record.

19.8.3.2 Initial medical examinations are required at the time of admission to the OTP. The examination may be conducted by the OTP physician, a primary care physician, or a physician extender as permitted by rule and law.

19.8.3.2.1 The examination shall include serology and other relevant tests. The examination shall be completed within fourteen (14) days following admission, including the review of results of serology and other tests.

19.8.3.2.2 Testing shall be conducted for tuberculosis, syphilis, and liver function. Further testing for Hepatitis B and C shall be available if indicated.

19.8.3.2.3 Voluntary screening for Human Immunodeficiency Virus (HIV) and other sexually transmitted infections shall be available. When appropriate, referral to other providers of these services shall be made and documented in the client record.

19.8.3.2.4 Clients shall be provided with all baseline testing recommended in pharmaceutical inserts of medications being considered for use.

19.8.3.2.5 All female clients of childbearing potential shall be tested for pregnancy upon admission to the OTP and as needed during the course of treatment. Pregnant clients shall be referred to prenatal care.

19.8.3.2.6 Results of examinations completed within the prior 12 months may be used for clients readmitted to a program within 3 months of discharge.

19.8.3.2.7 Clients transferring from another program shall complete all screening and admission procedures except in documented emergencies.

19.8.3.3 Initial assessments shall include a detailed bio-psycho-social evaluation, which shall provide supportive evidence that opioid agonist treatment is the medically appropriate treatment for the client. The evaluation shall include documentation of any previous treatment experiences.

19.8.3.4 Rehabilitation counseling services shall be provided by the OTP staff and shall be consistent with the client's treatment plans. The client record shall include documentation of the provision of counseling and the results of counseling. This counseling shall be in addition to the face to face evaluation done at the time of dosing.

19.8.3.4.1 During the first year of treatment, each client shall be provided at least one hour of individual counseling every 30 days. The

counseling may be provided in half hour sessions.

19.8.3.4.2 After one year of treatment, the need for counseling shall be evaluated and documented as part of the treatment plan. At minimum, clients who are not participating in group counseling shall be provided at least one hour of individual counseling every 30 days. Clients who are participating in group counseling at least once monthly shall be provided at least one hour of individual counseling every 90 days.

19.8.3.4.3 Clients admitted for supervised withdrawal services shall be provided two hours of individual counseling every 30 days. The counseling may be provided in half hour sessions.

19.8.3.4.4 Established clients who have initiated a medically supervised withdrawal following a period of dose stabilization or dose tapering plan shall be evaluated for counseling needs. The results of the evaluation and resultant plans shall be documented in the treatment plan.

19.8.3.4.5 OTPs shall make reasonable efforts to determine the client's eligibility when making referrals to other programs and to make referrals to programs for which the client is eligible.

19.8.3.5 Education on HIV and Hepatitis shall be provided to all clients. Additional education on other infectious diseases shall be provided by the OTP to clients, as dictated by client need. Education shall be documented in the client record.

19.8.4 Treatment Plans. Treatment plans shall be developed to describe the most appropriate combination of services and treatment.

19.8.4.1 The initial treatment plan shall be in writing and completed within 7 calendar days of admission. It shall be developed

and signed by the client, the primary counselor and the medical director.

19.8.4.2 The treatment plan shall include both short and long term goals, the services and/or steps necessary to achieve the goals, the frequency with which the services are provided, and the staff position or entity assuming responsibility for the provision of the services.

19.8.4.3 Updates to the plan shall be in writing and shall reflect the client's personal history, current needs, and degree of achievement of short and long term goals.

19.8.4.4 Updates shall be completed no less frequently than every 90 days. They shall be reviewed and revised if needed whenever there is a significant change in the client's status. They shall be signed by the primary counselor and client.

19.8.4.5 Treatment plans shall include the rationale for the use of the dosage plan. This shall be documented by a physician or physician extender. Initial doses of methadone shall not exceed 30 milligrams unless the physician documents the need for a higher dose.

19.8.4.6 Results of drug tests shall be documented in the client record and there shall be a clear indication in the client record that the results of drug testing have been reviewed and considered as part of the treatment planning process and decisions for take home dosing.

19.8.4.7 The medical director shall review and sign treatment plans on an annual basis.

19.8.5 Requirements for Maintenance Programs. All maintenance treatment programs shall operate as follows:

19.8.5.1 Population to be Served.

19.8.5.1.1 Addiction status. Clients shall be currently addicted to an opioid drug and shall have become addicted at least one (1) year before admission for treatment.

19.8.5.1.2 Age. Clients will be 18 years of age or older, unless approved by the Office of Substance Abuse, and the following requirements are met:

19.8.5.1.2.1 Clients under the age of 18 may not be admitted unless a parent, legal guardian, or responsible adult approved by OSA consents in writing to such treatment; and

19.8.5.1.2.2 Clients under the age of 18 are required to have had two documented unsuccessful attempts at short-term supervised withdrawal or drug-free treatment within a 12 month period.

19.8.5.1.3 Priority Clients. Pregnant clients and those who are HIV positive will be considered priority clients. Pregnant clients, regardless of age, may be placed on a regimen of opioid agonists, provided that the medical director certifies to the pregnancy, and documents that the treatment is medically justified.

19.8.5.1.4 Exceptions. If clinically appropriate, the OTP physician may waive the requirement of a 1 year history of addiction for clients released from penal institutions (if within 6 months after release), for pregnant clients (if the pregnancy has been certified) and for previously treated clients (up to 2 years after discharge).

19.8.5.2 Drug Testing Services. The OTP shall develop and follow policies and procedures, consistent with best practices and applicable law and rule, governing drug testing practices. The policy and procedure shall be approved by OSA. At minimum, drug testing policies shall include the following:

19.8.5.2.1 Prompt Testing. All drug testing samples shall be tested promptly. Testing facilities shall be qualified to conduct testing.

19.8.5.2.2 Drug Testing at Admission. All clients will have a drug test at admission. A positive test is not a requirement for admission to the OTP.

19.8.5.2.3 Required Screens. All required drug tests shall include screening for opiates, methadone, cocaine, benzodiazepines and other substances of abuse prevalent in the community.

19.8.5.2.3.1 Additionally, the drug test at admission shall include screening for cannabis.

19.8.5.2.3.2 Random drug samples shall be collected no less frequently than every 30 days unless the individual treatment plan indicates more collections are necessary. If the admission drug test was positive for cannabis, periodic screens for cannabis shall be conducted and documented.

19.8.5.2.3.3 Drug tests in addition to those required by this rule need include only those screens specific to the individual client's treatment needs.

19.8.5.2.4 Use of Results. Results of drug testing shall be used as a factor in making treatment decisions. Results of drug testing shall not be used in a punitive manner. There shall be a clear indication in the client record that the results of drug testing have been reviewed and considered as part of the treatment planning process and decisions for take home dosing.

19.8.5.2.5 Sample Integrity. Adequate and appropriate steps shall be taken to prevent falsification or substitution in sample collection.

19.8.5.2.5.1 The routine use of observation techniques such as cameras and windows is prohibited.

19.8.5.2.5.2 The use of observation shall be clinically substantiated and gender appropriate.

19.8.6 Staff Requirements.

19.8.6.1 The Medical Director shall be a physician licensed to practice in the State of Maine, and in addition shall be certified by the American Society of Addiction Medicine (ASAM) or otherwise qualified through education, experience and training in addictions.

19.8.6.1.1 The medical director shall assume responsibility for administering all medical services performed by the OTP, either by performing them directly or by delegating specific responsibility to authorized program physicians and healthcare professionals functioning under the medical director's direct supervision. The medical director shall meet the requirements described at Section 10.0 of these rules.

19.8.6.1.2 The medical director shall review all treatment plans at least once annually and indicate written approval.

19.8.6.1.3 The medical director shall review and approve in writing all OTP policies.

19.8.6.1.4 The OTP shall notify the Office of Substance Abuse of the resignation or replacement of a Medical Director within five days of such resignation or replacement.

19.8.6.2 Physician extenders may be utilized at an OTP under the following conditions:

19.8.6.2.1 Physicians Assistants (PAs) may practice as described at 02-373 Code of Maine Rules (CMR) Chapter 2, as amended, under the supervision of the Medical Director.

19.8.6.2.2 Nurse Practitioners (CNPs) may practice as described at 02-373 CMR Chapter 3, as amended, and 02-380 CMR Chapter 8, as amended, under the supervision of the Medical Director.

19.8.6.3 The Nursing Supervisor will be a Registered Professional Nurse licensed according to Maine law and who will have education, experience and training in the treatment of substance abuse or mental health or both. The nursing staff may include Licensed Practical Nurses licensed according to Maine law.

19.8.6.4 The Pharmacist will be licensed to engage in the practice of Pharmacy in the State of Maine.

19.8.6.5 There shall be a Clinical Supervisor who meets the requirements of Section 11.0 of these rules.

19.8.6.6 OTPs shall employ an adequate number of counselors, qualified pursuant to 32 M.R.S.A. Chapter 81, as amended.

19.8.6.6.1 Caseloads for individual counselors shall be comprised of clients in varying stages of treatment.

19.8.6.6.2 Caseloads shall be prorated for counselors employed by the OTP on a part time basis.

19.8.6.6.3 Caseloads shall not exceed 50 clients for any counselor employed by the OTP on a full time basis.

19.8.6.6.4 Unless pre-approved by OSA, caseloads shall not exceed 35 clients for counselors employed by the OTP on a full time basis who have not completed 2000 hours of substance abuse practice under clinical supervision.

19.8.6.7 Training. In addition to the training requirements of Section 13.4.1 and 13.4.2 of these rules, staff will receive:

19.8.6.7.1 An intensive program of training specific to opioids and opioid agonist issues. The training plan will be developed by the OTP and staff will have updates annually;

19.8.6.7.2 Training on the subject of HIV infection and treatment of HIV infected clients; and

19.8.6.7.3 Training on the subject of Hepatitis B and C and treatment and prevention of Hepatitis.

19.8.6.8 Background Checks. Background checks, including but not necessarily limited to conviction of offenses related to the possession, use, sale or distribution of controlled substances shall be conducted. The expense of such background checks shall be borne by the OTP. Persons who have been convicted of any felony, or an offense related to the possession, use, sale, or distribution of controlled substances, may be employed by the OTP in a position with access to a scheduled or prescription drug or controlled substance only if the OTP documents in the person's personnel file the offense and sanction, the OTP's assessment of the seriousness of the factual basis for the offense, and the agency's rationale for hiring and/or retaining the person. OTPs shall not engage in any capacity any person if there exists a reasonable articulable suspicion of current use of illicit substances or criminal activity related to possession, use, sale or distribution of controlled substances.

19.8.7 Medication Administration at the OTP. OTPs shall develop and follow policies and procedures that are adequate to ensure that treatment medication used by the program is administered and dispensed in accordance with approved product labeling and that the following dosage form and initial dosing requirements are met:

19.8.7.1 The OTP shall utilize an effective procedure to ensure that client identity and the correct dose and medication are being verified prior to medication administration. Ingestion and swallowing shall be observed by the staff person who administered the medication, who shall document the administration of the medication in the record.

19.8.7.2 At the time of dosing there shall be a face to face clinical evaluation by qualified staff that may be short in duration. If the evaluation indicates the need for further evaluation

or intervention, the evaluation or intervention shall be documented in the client record.

19.8.7.3 Medication may be withheld when the OTP physician or physician extender determines that administration of the medication would not be medically or clinically appropriate. The withholding of medication shall be substantiated in the record and signed by the authorizing practitioner.

19.8.7.4 When clients transfer from one OTP to another, medication doses may be communicated from medical personnel at the discharging program to medical personnel at the admitting program, as may be permitted by applicable law and rule.

19.8.7.5 OTPs shall develop and follow policies and procedures regarding courtesy dosing. Policies shall address situations in which the OTP is requesting courtesy dosing for a client and when it is providing courtesy dosing. Policies shall be based on best practice standards. Policies shall address verification of client identify, verification of dose and medication, documentation of medication administration.

19.8.8 Unsupervised or Take-Home Use. The OTP shall develop and follow policies and procedures regarding take home privileges. The policy shall ensure the following:

19.8.8.1 All decisions regarding take home privileges shall be documented in the client record and shall comply with the requirements cited in 42 CFR Chapter 1, Subchapter A, Part 8.

19.8.8.2 Medication shall be dispensed only in oral form.

19.8.8.2.1 Methadone shall be dispensed in liquid form only in single dose containers, or in dry form only in multiple dose containers.

19.8.8.2.2 Other medications shall be dispensed according to federal regulations and manufacturer's recommendation.

19.8.8.3 Clients will not be allowed take home privileges during the first ninety (90) continuous days of treatment.

19.8.8.4 After ninety (90) continuous days of treatment, clients may be allowed take home privileges no greater than the following schedule:

19.8.8.4.1 From the ninety first (91st) to the one hundred eightieth (180th) continuous days of treatment, one take home dose per week is permitted;

19.8.8.4.2 From the one hundred eighty first (181st) to the two hundred seventieth (270th) continuous days of treatment, two take home doses per week are permitted;

19.8.8.4.3 From the two hundred seventy first (271st) to the three hundred sixtieth (360th) continuous days of treatment, three take home doses per week are permitted;

19.8.8.4.4 From the, three hundred sixty first (361st) continuous day of treatment onward six take home doses per week are permitted.

19.8.8.5 Exceptions to take home schedules may be approved by OSA. OTPs are responsible for providing documentation supporting the clinical justification for requested exceptions. Requests for exceptions and the documentation required to demonstrate clinical justification shall be delivered to OSA in the form and format as may be required by OSA no later than five business days prior to the day the requested exception is to take effect.

19.8.8.6 In emergencies, take home doses may be provided under the following circumstances:

19.8.8.6.1 The program has made reasonable, documented attempts to contact OSA for permission;

19.8.8.6.2 The nature of the emergency has been verified by the program and documented in the record;

19.8.8.6.3 The client has met the minimum requirements for take home privileges; and

19.8.8.6.4 The program director and the medical director document this decision in the record. Documentation of this decision shall be submitted to OSA by the program director within one business day.

19.9 Detoxification - Social Setting

19.9.1 Definition

19.9.1.1 Detoxification - Social Setting is a component which provides persons having subacute problems related to alcohol or drug use/abuse with immediate medical evaluation, diagnosis, and care recognizing that the emphasis is more on the counseling program as a treatment agent as opposed to professional intervention and/or medical detoxification. The program shall provide services on a 24-hour per day basis.

19.9.2 Requirements

19.9.2.1 The program shall describe the Detoxification - Social Setting component in detail. The description shall include:

19.9.2.1.1 Admission criteria which clearly detail the factors for selecting clients who are appropriate for this level of service;

19.2.1.2 A statement of the typical services to be provided, including the length and amount of time for each service.

19.9.3 Provision of Services

19.9.3.1 The Detoxification - Social Setting program shall provide 24-hour availability of:

19.9.3.1.1 Access to immediate medical monitoring on a 24-hour per day basis;

19.9.3.1.2 Supervision of clients by properly trained staff until the client is no longer intoxicated;

19.9.3.1.3 Referral to other services not provided by the Detoxification Social Setting component.

19.9.3.2 The program shall also provide:

19.9.3.2.1 A physical examination by a physician or physician's assistant within 48 hours of admission;

19.9.3.2.2 Written arrangements for hospital care for medical services beyond the capability of the program;

19.9.3.2.3 Special diets as needed;

19.9.3.2.4 Individual and group counseling, or provision of such counseling through other resources;

19.9.3.2.5 a supportive environment which offers a controlled group living experience;

19.9.3.2.6 opportunities for family involvement and referral of family to counseling when appropriate;

19.9.3.2.7 motivational counseling to seek further treatment;

19.9.3.2.8 planning for and referral to further substance abuse treatment.

19.9.4 Staff

19.9.4.1 Every Detoxification - Social Setting program shall have 24-hour on-site coverage by staff.

19.9.4.2 Staff involved with clients shall be highly skilled, specially selected, and trained to recognize impending alcohol/other drug emergencies, and have the capability to refer clients evidencing such impending emergencies to an alternative medical emergency back-up facility.

19.9.4.3 All personnel providing client care shall have completed, prior to employment, the standard Red Cross first aid class and cardiopulmonary resuscitation (CPR) certification, or its equivalents, and shall complete, within six months of their employment, the advanced Red Cross first aid class or its equivalent.

19.9.4.4 Clinical supervision-shall be provided to all staff on weekly basis.

19.9.5 Medication

19.9.5.1 Nothing in this section shall be construed as authorizing or permitting any person to do any act outside of federal or state laws.

19.9.5.1.1 No medication should be taken without medical direction. If the client brings drugs into the program for previously existing disorders:

19.9.5.1.1.1 The actual medication must be identified by a physician or a pharmacist, and

19.9.5.1.1.2 A physician must approve the prescribed dose, and

19.5.1.1.3 These drugs shall be stored in accordance with Section 4.04 L of these regulations.

19.9.5.2 Clients shall self-administer their medication. Self-administration of medication is defined as giving the client the opportunity of taking medications according to prescription so long as the client is determined to be mentally and physically capable of doing so by the medical director.

If the medical director determines the client needs supervision in the administration of the medication, he/she shall so indicate in the medical orders.

19.9.6 Case Record

19.9.6.1 The program shall document the progress of each client in the case record on not less than a daily basis.

19.9.7 Program Completion Criteria

19.9.7.1 Programs shall describe in detail the indicators used to determine satisfactory completion of the detoxification process.

19.9.7.2 Programs shall describe conditions under which clients will be discharged before successful program completion.

19.9.8 Transportation

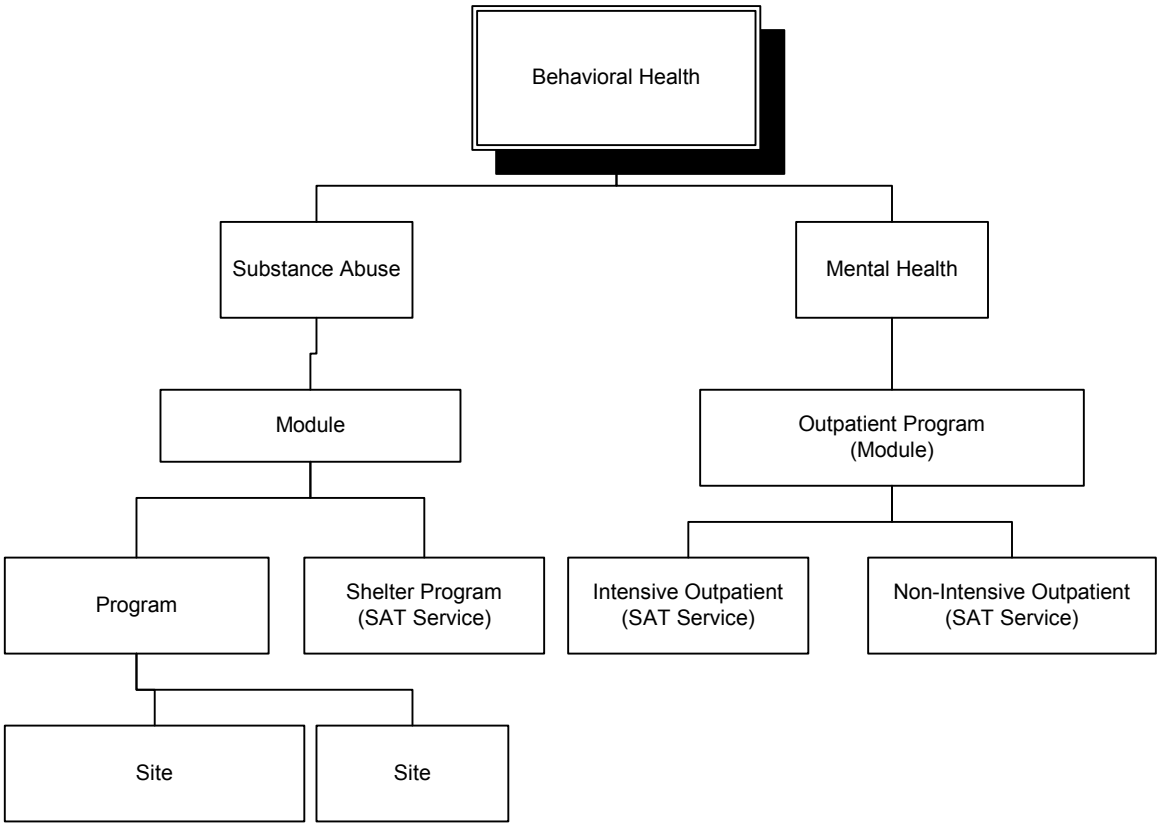
19.9.8.1 Transportation support shall be available 24 hours a day. A written agreement shall provide for transportation between the program and emergency health care facilities.

19.9.9 Nutritional Services

19.9.9.1 In addition to the requirements in Section 4.04 of these regulations, the kitchen shall be capable of providing for preparation of snacks, soup and sandwiches decaffeinated coffee, and juices. which shall be available for clients.

ADDENDUM I
ORGANIZATIONAL DIAGRAM

The following diagram is included to clarify distinctions between agencies, components, modules, substance abuse treatment services, and sites.



Agency: An incorporated firm, partnership, association, or organization licensed/certified under these regulations that provides at least one substance abuse treatment service.

Component: A category of comprehensive services within an agency, such as substance abuse services or mental health services, that includes one or more treatment modules.

Module: A service category found under a licensing component. Outpatient or residential programs are examples of modules in a substance abuse component.

Substance Abuse Treatment Service: A specific ongoing module of treatment provided by an agency.

Site: The physical location of a substance abuse program.